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Historical Institutionalism and the Politics of a Knowledge Economy

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A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Political Science

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Historical Institutionalism and the Politics of a Knowledge Economy

Abstract

This dissertation examines the role that domestic institutions can play in the implementation of international intellectual property rights standards. In doing so, it argues that the path dependence of existing institutions can alter how international standards are actually implemented on the ground. It further argues that this altering of standards can create feedback effects that influence related state policies and the international standards themselves. This argument adds to the IPE literature on the creation of international intellectual property (IP) rights, which thus far, has tended to focus primarily on international-level negotiations rather than national-level implementation. It challenges the dominant 'market power' explanation that emphasizes the role of economic power in setting international regulatory standards. It does so by examining a critical case study of Canada and its implementation of trade-related intellectual property standards. Canada is a critical case due to its high trade dependence on the United States, which makes it 'least likely' to resist US market power. The dissertation shows how Canada has managed its adoption of trade-related IP standards through institutional layering and conversion strategies at various levels of governance. The analysis argues for, and significantly supports, the value of historical institutionalism in the study of international political economy.

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Abbreviations

ANDA	FDA Abbreviated New Drug Application
BERD	Business Enterprise Research and Development
BIO	Biotechnology Innovation Organization
CADTH	Canadian Agency for Drugs and Technologies in Health
CAFC	United States Court of Appeals for the Federal Circuit
CAPCA	Canadian Association of Provincial Cancer Agencies
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CDEC	Canadian Drug Expert Committee
CDMA	Canadian Drug Manufacturers' Association
CDR	Common Drug Review
CEDAC	Canadian Expert Drug Advisory Committee
CER	Comparative Effectiveness Research
CETA	Comprehensive Economic and Trade Agreement
CETS	Conseil d'Evaluation des Technologies de la Santé du Québec
CGPA	Canadian Generic Pharmaceutical Association
CIHI	Canadian Institute for Health Information
CIPO	Canadian Intellectual Property Office
CLHIA	Canadian Life and Health Insurance Association
CPI	Consumer Price Index
CPUC	Canadian Patent Utility Coalition
DIN	Drug Identification Number
DNL	Do Not List
DVA	US Department of Veterans Affairs
EBM	Evidence Based Medicine
EC	European Commission
F/P/T	Federal, Provincial and Territorial
FC	Federal Court (Canada)
FCA	Federal Court of Appeal
FDA	US Food and Drug Administration
FDI	Foreign Direct Investment
FSS	US Federal Supply Schedule
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GIPC	US Chamber of Commerce, Global Intellectual Property Center
HDAP	Human Drug Advisory Panel
HHS	US Department of Health and Human Services
HI	Historical Institutionalism
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
HTM	Health Technology Management
ICER	Incremental Cost-Effectiveness Ratio
iJODR	Interim Joint Oncology Drug Review

INAHTA	International Network of Agencies for Health Technology Assessment
IOs	International Organizations
IP	Intellectual Property / Intellectual Property Protection
IPC	International Price Comparison
IPE	International Political Economy
IR	International Relations
ISDS	Investor state dispute settlement
MNE	Multinational Enterprise
NAFTA	North American Free Trade Agreement
NGOs	Non-Governmental Organizations
NHS	UK National Health Service
NICE	UK National Institute for Health and Care Excellence
NOC	Notice of Compliance
OECD	Organisation for Economic Co-operation and Development
pCODR	Pan-Canadian Oncology Drug Review
PCORI	US Patient-Centered Outcomes Research Institute
pCPA	pan-Canadian Pharmaceutical Alliance
PCT	Patent Cooperation Treaty
pERC	pCODR Expert Review Committee
PhRMA	Pharmaceutical Research and Manufacturers of America
PM(NOC)	Patented Medicines (Notice of Compliance) Regulations
PMPI	Patented Medicines Price Index
PMPRB	Patented Medicine Prices Review Board
PPRI	Pharmaceutical Pricing and Reimbursement Information
PTR	Patent Term Restoration
QALY	Quality-Adjusted Life Years
R&D	Research and Development
RBP	Reference-Based Pricing
RCC	US-Canada Regulatory Cooperation Council
RR	Reasonable Relationship
Rx&D	Canada's Research Based Pharmaceutical Companies
SCC	Supreme Court of Canada
SEC	US Securities and Exchange Commission
TCC	Therapeutic Class Comparison
TNCs	Transnational Corporations
TPP	Trans-Pacific Partnership
TRIPS	Trade Related Aspects of Intellectual Property Protection
TTIP	US-EU Transatlantic Trade and Investment Partnership
UNESCO	United Nations Educational, Scientific and Cultural Organization
USPTO	US Patent and Trademark Office
USTR	United States Trade Representative
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Chapter 1 - Introduction

Facing international competitive pressures, nations have increasingly turned to the “knowledge economy” for new sources of wealth, prosperity and employment. Enhancing intellectual property protection (IP) is often a key pillar of this effort. IP has become a central component of multilateral trade agreements towards an increasingly global set of standards. The Office of the United States Trade Representative (USTR) has proved particularly successful in promoting US IP-related interests internationally through trade agreements such as the North American Free Trade Agreement (NAFTA) and by inserting Trade Related Aspects of Intellectual Property Protection (TRIPS) into the Uruguay Round of World Trade Organization (WTO) negotiations (Sell 2003; Tyfield 2008).

The emergence of the international intellectual property regime begs the research question: are dominant theories of international political economy such as “market power” sufficient to explain the design and implementation of international intellectual property standards? This is an important question given IP’s clear distributional implications and is a subset of a broader research question in international political economy (IPE) that asks: which theories best explain international regulatory regimes? In examining these questions, this dissertation adopts an historical institutionalist approach which, in contrast to other theories of international relations, views international

regulatory regimes as historically cumulative and as arising out of domestic standards. It argues that historical institutionalism is not in fact “bunk.”¹

For example, a state-centric realist approach would argue that intellectual property standards, like many international regimes, are created through US leadership. Particularly important to the US’s effectiveness as a *standard-maker* is its market power (Drezner 2007; 2010). Access to the US market acts as a strong incentive for other *standard-taker* nations to adopt US-style IP standards when tied to trade treaties. Neoliberal institutionalism also takes a state-centric approach but places greater emphasis on the role of agency, coalition-building and issue linkage among states. Opening the black box of the state, neopluralist and Gramscian approaches, in contrast, would emphasize the role and power of US transnational corporations (TNCs) as well as neoliberal ideas on property rights. Similarly, some liberal constructivists have looked to the role of norm formation and socialization under power asymmetry as a source of determinacy (Morin et al. 2011). Finally, some IPE scholars have argued that historical institutionalism provides a useful set of tools to help understand how international regimes are created. Specifically, historical institutionalism (HI) stresses the importance of national characteristics, domestic institutional structures, and the sequencing of regulatory capacity in explaining the establishment of international regimes (Farrell and Newman 2010; Sell 2010).

While the creation of TRIPS and their associated IP standards have been studied in the context of the US as a standard-maker, there is little agreement on theoretical

¹ The question “Is Historical Institutionalism Bunk?” was raised by Drezner (2010) in response to some early articulations of historical institutionalism in IPE.

² Per North (1990), this study employs a broad and inclusive definition of institutions as “humanly devised constraints that shape human interaction... Institutional change shapes the way societies evolve through time and hence is key to understanding historical change” (3). For the purposes of greater breadth,

approaches and an acknowledged gap regarding the actual implementation of these standards across specific national contexts (Drezner 2010, Matthews 2002; Sell 2010; Alter and Meunier 2009). For example, Susan Sell notes that, “while many scholars have analyzed how actors reach international agreements, we know far less about agreements’ implementation” and the “exact causal mechanisms through which policies are communicated” (Sell 2010, 780). Reflecting this gap in the literature, the dissertation examines the role that domestic institutions can play in the implementation of international IP standards. In doing so, it argues that the path dependence of existing institutions² can alter how international standards are actually implemented on the ground. It further argues that this altering of standards can also create feedback³ effects that influence related state policies and the international standards themselves.

In other words, standard-maker countries do not unilaterally set international IP standards. The process of standard creation does not end when the negotiating parties sign an international agreement. By focusing on agreement implementation and the evolution of standards over multiple agreements, this dissertation offers a new way of thinking about standard setting. It is proposed that past experience with regulatory

² Per North (1990), this study employs a broad and inclusive definition of institutions as “humanly devised constraints that shape human interaction...Institutional change shapes the way societies evolve through time and hence is key to understanding historical change” (3). For the purposes of greater breadth, this quote excludes North’s discussion of incentives.

³ The concept of policy *feedback* is linked to institutional path dependence and has different uses and definitions. Generally, this refers to the tendency of a political or institutional event, critical juncture, or power structure to naturally reinforce itself over time. Thelen (1999) provides a few different conceptions and notes “once a set of institutions is in place, actors adapt their strategies in ways that reflect but also reinforce the ‘logic’ of the system” (Thelen 1999, 392). An alternative view posits that institutions “reflect, and also reproduce and magnify, particular patterns of power distribution in politics” (Ibid, 394). Pierson has explained policy feedback in similar terms: “when effect becomes cause,” when “policies create politics,” or when “policies generate resources and incentives for political actors” (Pierson 1993). The present analysis identifies different forms of feedback according to the level governance or institution where it becomes apparent (i.e. regulatory, judicial, procurement, international relations). Feedback usually involves a self-reinforcing impulse and can manifest in institutional layering and conversion strategies (Thelen 2003). However, this institutional reproduction may act to repel or resist some other political force or phenomenon. As such, a broad and inclusive conception of feedback is employed herein.

standards and existing institutions can greatly impact negotiating positions, negotiated outcomes and the implementation process. Implementation further shapes the real-world regulatory effects of the regime.

To evaluate these points, the dissertation examines the case of Canada, a country that has adopted US-style intellectual property norms under TRIPS and NAFTA.⁴ On the surface, this case would appear to correspond to a market-power explanation for the creation of intellectual property standards given Canada's considerable dependence on the US market and adoption of US-style IP rights. However, a pure market power explanation is called into question when taking a closer look at TRIPS/NAFTA implementation and related policies. Canada shows that domestic regulatory and legal institutions are formed or existing institutions are converted to mitigate the local effects of those international standards.

Background

The evolution of international intellectual property standards is perhaps one of the most politically contentious areas of international regulation. Intellectual property protection fundamentally alters a given distribution of wealth, creating benefits for technology producers and owners, and creating costs for consumers of those technologies. Canada is a somewhat reluctant participant in the international intellectual property regime and its standards. Access to the US market was a powerful motivator for bringing Canada closer

⁴ While there are some differences regarding the provisions for patents between TRIPS and NAFTA, these parallel agreements were part of the same US advocacy push and should be considered together. Under Bill C-22 (1987) linked to the Canada-US Free Trade Agreement, Canada implemented 20 years of patent protection in 1989 in advance of those standards being mandated under TRIPS. Key IP language from a draft of TRIPS was directly reproduced into NAFTA's IP- Chapter (Chapter 17). Bill C-91 (1992) the *Patent Amendment Act* implemented NAFTA and TRIPS provisions jointly (Norton Rose 2012; Douglas and Jutras 2008). These are treated herein as part of the same overarching group of extended intellectual property protections.

to US standards in the late 1980s and 1990s. This included the abolition of most compulsory licensing, the extension of patent protection from 17 to 20 years, implementation of a US-style patent linkage regulation, and the introduction of clinical data protection for pharmaceuticals (Norton Rose 2012; Douglas and Jutras 2008).

Canadian institutions have acted to constrain the effects of these more protective US-style standards. Canada's introduction of US IP standards marked an important divergence from historical practice that triggered a series of institutional responses. Some responses were immediate including measures explicitly tied to domestic implementation such as regulatory price controls. This was a deliberate policy offset attached as a compromise to domestic interest groups and subnational governments. Other responses, such as post-TRIPS case law, materialized over a longer time horizon following implementation. In Canada's case, the manner in which the standards were implemented allowed considerable flexibility for subsequent interpretation. This set the stage for a clash between international and domestic standards.

Canada's uneasy relationship with intellectual property rights and knowledge economy promotion reflects its historical industrial composition and output. By OECD standards, Canada's knowledge economy output is quite low.^{5,6} Canada has fared

⁵ As measured by Technology Balance of Payments: Receipts (TBP), Canada receives around \$2.9 billion (2010) or approximately 0.19% of GDP. The US is the international leader for this metric at \$113.1 billion (2011) or 0.73% of GDP (OECD 2013, 88, 103). Canada has considerable economic strength in banking and resource sectors but its technology sectors have clearly lagged. Other comparators include the UK \$49 billion (2% of GDP); Sweden \$29 billion (3.9% of GDP); Netherlands \$39 billion (4.8% of GDP); Italy \$13.7 billion (0.63% of GDP); Spain \$9.9 billion (0.67% of GDP); Switzerland \$21.1 billion (3.2% of GDP); and Finland \$10.7 billion (4.1% of GDP).

⁶ This still nascent metric compiled by the OECD reflects an aggregation of a national economy's capacity to convert real-world economic value on those products subject to intellectual property protections as measured by the flows received from technology and knowledge-based products. According to OECD methodology, the Technology Balance of Payments "registers the commercial transactions related to international technology transfers. It consists of money paid or received for the acquisition and use of patents, licenses, trademarks, designs, know-how and closely related technical services (including technical assistance) and for industrial R&D carried out abroad, etc." OECD Technology Balance of Payments

particularly poorly in attracting and incenting Business Enterprise Research and Development (BERD). Between 2006 and 2011, BERD in all Canadian industrial sectors declined 9% as compared to a 19% *increase* in the OECD (OECD 2013).⁷ These recent declines have been skewed toward business sectors particularly impacted by new technology and intellectual property protection.⁸ While the exact causes of Canada's poor research and development (R&D) investment performance have not been decisively established, an entrenched "branch-plant" technological dependency is likely a factor (Smardon 2014, 51). Regardless of historical factors, Canada's IP regime is clearly not producing investment results. This is framed by IP advocates as justification for a modernization or strengthening of TRIPS-era standards, and framed by opponents of IP as evidence of its policy failure.

There is an explicit desire on the part of policy makers to increase business investment in the knowledge economy. However, IP protections are also scrutinized for their cost implications. This is particularly the case for the pharmaceutical sector where there is considerable contestation over IP standards and the perceived link to public health care cost escalation.^{9,10} Canada's tepid performance in the knowledge economy and

database, May 2013, as cited in: OECD, *Main Science and Technology Indicators*, 2013, 88; 103. All figures in current US dollars. GDP figures calculated from World Bank GDP data, accessed September 14, 2014 <http://data.worldbank.org/indicator/NY.GDP.MKTP.CD>

⁷ At current prices adjusting for purchasing power parity. In 2008, total Business Enterprise Research and Development (BERD) spending in Canada was just 1 percent of GDP, well below the OECD average of 1.6% placing it 18th among those 31 countries (Jenkins et al., 2012, 2-6).

⁸ A decline in pharmaceutical-sector BERD accounts for much of the total BERD decline. According to OECD data, between 2006 and 2011 BERD conducted in the pharmaceutical industry declined 43%. BERD performed in the pharmaceutical industry as a percentage of total BERD in Canada declined 37%. Between these years, total BERD in Canada declined by \$1.18 billion and pharmaceutical industry BERD declined by \$383 million, thus total pharmaceutical industry R&D decline as a percentage of total Canadian BERD decline was 32% (OECD 2013). In other words, at least one third of Canada's most recent decline of business R&D investment could arguably be attributed to declines in one technology sector. Author calculation based on OECD data.

⁹ For example, in order to secure provincial government support for the Comprehensive Economic and Trade Agreement (CETA) with the EU, Canada's federal government committed to compensate

its historical aversion to intellectual property rights has seen the development of a strong institutional response to the international IP regime, despite US pressure and market power. Overtly, the basic provisions required to be TRIPS/NAFTA compliant have been met including 20-years of patent protection and no routine compulsory licenses. However, regulatory, judicial, and procurement institutional responses have acted to shape and limit the IP regime's real-world effects.¹¹

Methodology

This dissertation employs process tracing under a critical or crucial case research design. Critical case design is an approach that is logically structured to leverage a small number of cases or a single critical case to examine a theory (Eckstein 1975; Levy 2008; Bennett and Checkel 2015a). The incentives for Canada to acquiesce to US standards are clear and self-evident. Fully 70.3%¹² of Canada's goods and services export market is

provinces for cost increases resulting from its arguably moderate expansion of intellectual property rights for pharmaceuticals. "Should concessions to the EU in this area generate cost impacts on provincial and territorial governments, the federal government is prepared to address these incremental cost impacts." Government of Canada, 2013 "Technical Summary of CETA Agreement in Principle," accessed September 20 2014, <http://www.actionplan.gc.ca/sites/default/files/pdfs/ceta-technicalsummary.pdf>; See also, Federal Trade Minister Fast and Chief CETA Negotiator Steve Verheul testimony, House of Commons, Standing Committee on International Trade, November 7, 2013, accessed September 20, 2014, <http://www.parl.gc.ca/content/hoc/Committee/412/CIIT/Evidence/EV6293140/CIITEV04-E.PDF> Back in 1987, the federal government had made a similar commitment to provinces offering them \$100 million over four years to offset potential costs to provincial drug plans. Minister Harvie Andre, Statements to House Committee Study on Bill C-22, Tuesday, December 16, 1986, (1545).

¹⁰ This assurance was made following a joint provincial campaign opposing expanded intellectual property protections as part of CETA and as a result of deep provincial involvement in negotiation rounds and strategic planning (Standing Committee on International Trade 2014, 3); Heather Scofield, "Provinces Join forces to keep EU free-trade deal from upping drug costs" *Globe and Mail*, June 3, 2012.

¹¹ Specifically, as discussed below, Canada was able to 1) implement a price control mechanism in parallel with its trade-related intellectual property commitments; 2) implement uniquely Canadian patent adjudication mechanisms; 3) preserve Canada-specific definitions of patentable utility at odds with international regime language; 4) transform existing procurement mechanisms to constrain the impact of increased patent protection for government insurance plans; and, 5) use the experience with NAFTA to strengthen negotiating positions for subsequent trade and IP agreements.

¹² Department of Foreign Affairs, International Trade and Development, "Canada's State of Trade: Trade and Investment Update 2011" accessed September 20, 2014,

dependent on the US, which reflects a significant dependence for a small market of just 34 million people. Therefore, to the extent that Canada is strongly dependent on the US economy, we would expect high incentives for Canada to adopt the US favored standards when accompanied by any strong US pressure for reform. If Canada does not, or significantly mitigates those standards as argued herein, then the market power explanation would seem incomplete. Levy characterizes this analytical approach as “Sinatra inference” or “If I can make it there, I’ll make it anywhere” (Levy 2008, 12). The core advantage of critical cases is the extent to which a small n can have asymmetrical inferential value in evaluating a hypothesis. Canada is used as a critical case for the market power theory.

An alternate way of thinking about this is from the perspective of the opposite hypothesis, that Canada as a standard-taker should be least likely to show strong institutional path dependence. Levy (2008) describes the logic underpinning this approach to critical cases:

If one’s theoretical priors suggest that a particular case is unlikely to be consistent with a theory’s predictions—either because the theory’s assumptions and scope conditions are not fully satisfied or because the values of many of the theory’s key variables point in the other direction—and if the data supports the theory, then the evidence from the case provides a great deal of leverage for increasing our confidence in the validity of the theory (Levy 2008, 12).

The expectation for Canada would be high compliance with the US-style protections and that existing Canadian institutions and responsive policy feedbacks would not be determinative of policy outcomes. If this expectation were disconfirmed than a market-power explanation would be called into question. Similarly, this could lend support to an

historical institutional hypothesis if path dependence, sequencing and feedbacks are shown to play an important role where they would not be expected.

Within the critical case of Canada, the research design also leverages and traces critical case *policies* that were most favorable to the US and thus should be most likely to support the market power hypothesis. This “critical case, critical policy” approach applies to intellectual property protection in general, and specifically to pharmaceutical patents, where it is often assumed that Canada has essentially bowed to US pressure.¹³ The approach is perhaps most apparent in Chapter 4 where US-style patent linkage policy is shown to be implemented with surprising favorability to Canada.¹⁴

Case Selection

The choice of Canada under a critical case study design is appropriate for this research question given the overwhelming and multidimensional dependence on the US with respect to trade, industrial integration, defense, and technological production.¹⁵ As discussed, it was selected because it is most likely to support a market power hypothesis and least likely to support an historical institutionalist hypothesis. We would not expect

¹³ See Senate Debates on Bill C-22, June 25, 1987, in particular Senator L. Norbert Theriault, (at 1404). Also, it should be noted that Canada has fairly high prescription drugs spending per capita that does not make it an obvious first choice for an argument that domestic institutions constrain international patent protection regime standards. This issue of the magnitude of Canadian institutional constraints is addressed in Chapters 6 and 7. It is argued that Canadian market fragmentation and the private market portion of total prescription drug spending accounts for much of this. Around half of prescription drug spending is on non-patented drugs and middlemen mark-ups by the wholesale and pharmacy industries. The impacts of patent protection on actual ex-factory drug costs are actually surprisingly constrained in Canada, particularly in the highly scrutinized public market.

¹⁴ Additionally, a concise within-case comparison of Canadian public institutions versus the Canadian private market is conducted in Chapter 6 to explore the significance and magnitude of public institutional capacity.

¹⁵ As a small, open nation, Canada’s high reliance on access to the US market is a structural political-economic feature that plays a role in many contemporary bilateral issues. These include: the Keystone XL Pipeline; Beyond the Border initiative and the Regulatory Cooperation Council (RCC); US “Buy America” procurement policy; the Trans-Pacific Partnership (TPP) negotiation; and indirectly, via many foreign policy priorities where Canada often works strategically as a normative support to US policy via participation in international coalitions.

Canada to significantly mitigate the force and effect of international standards advanced by its powerful trading partner.¹⁶

On this point of capacity and power asymmetry, Canada is more appropriate than many alternatives. For example, the EU is the focus of some of the historical institutionalism literature arguing that standard setting is a function of a system's attractiveness due to its "regulatory capacity" (Bach and Newman, 2010). However, the EU is a major market and regulatory power and thus is an inherently less persuasive alternative to Canada when arguing the importance of institutional over market power factors. Canada is also more appropriate than some emerging economies such as China given its growing power and increasing ability to project and protect its interests independent of the US pressure. Furthermore, Canada's considerable *trade* dependence is highly relevant given that intellectual property regulation is now inseparably linked to trade agreements.

The hypothesis is generated from explicit gaps in the IPE literature regarding implementation¹⁷ and the failure of dominant theories in IPE to address issues beyond the agreement of an international treaty. Levy and others note that selection bias in case study research can be minimized "if scholars make a serious effort to test their explanations against alternative interpretations...[by specifying] leading alternative interpretations, the observable implications of each, and the evidence that would lead them to accept or reject each explanation" (Levy 2008, 9; see also Bennett and Checkel

¹⁶ Furthermore, Canada traditionally had very weak intellectual property protection institutions and this lack of a strong preexisting capacity does not predict strong policy feedbacks. This is because prior to trade-related IP rights, Canada did not have an entrenched policy option to advance as an alternative to US IP proposals. Following TRIPS implementation, some scholars have upheld Canada's establishment price control institutions as a model for emulation (Morin and Bourassa Forcier 2011, 202-5).

¹⁷ Discussed in Chapter 2 below.

2015a, 24). This dissertation provides such an analysis of alternatives with a particular, but not exclusive, emphasis on market power. Despite market power expectations, the practical reality gleaned through in-depth process tracing suggests that Canada's constellation of regulatory and legal institutions is resilient and act as a formidable source of power. The implications for theory are that we cannot sacrifice accuracy for the purposes of achieving parsimony on one theoretical approach. Multiple perspectives including historical institutionalism are required to explain regime formation, domestic implementation, and the evolution of standards over time.

Process Tracing

This dissertation traces the process of TRIPS and NAFTA implementation in Canada. Process tracing is defined as “the use of evidence from within case studies to make inferences about historical explanations” and was derived from cognitive decision-making approaches (Bennett and Checkel 2015a, 5). It has been applied in both ideographic and structural-level analysis (Ibid). Process tracing involves “intensive analysis of the development of a sequence of events over time, [and] is particularly well-suited to the task of uncovering intervening causal mechanisms and exploring reciprocal causation and endogeneity effects” (Levy 2008, 6). The technique has emerged as an important tool in the arsenal of qualitative and multi-method researchers and is often used productively in the empirical evaluation of critical case designs.

Process tracing has been proposed by the qualitative and multi-method revolution in American political science as a methodological correction for the problem of equifinality; the reality that there are often multiple causal paths to a given outcome (Bennett and Checkel 2015, 19). One approach involves the exploration of necessary and

sufficiency conditions. For example, market power may be a necessary condition for regulatory bargaining leverage but it may not be a sufficient condition to induce change (Farrell and Newman 2010, 614). Clearly to be routinely successful as a regime-maker, market power is required, but it is a partial explanation to a partial question: one that neglects domestic causes, domestic effects, and the resultant policy feedbacks that may have a legacy effect on future outcomes.

Key figures in the emergence of the process tracing movement have insisted that it must be practiced more systematically and with explicit attention to criteria for what constitutes *good* process tracing (Bennett and Checkel 2015b, 260-1).¹⁸ Their criteria are exacting and logically require the adoption of a meta-theoretical approach such as *scientific realism* or its subset *critical realism* that is consistent with the possibility of observable and unobservable causal mechanisms (Bennett and Checkel 2015a, 21 Jackson 2011, 76; Chernoff 2009, 388; see also Wendt 1999; Chernoff 2002).¹⁹ Furthermore, they caution that scholars must consider the broader “structural discursive contexts” and probe alternative causal pathways to those central to the hypothesis (Bennett and Checkel 2015a, 21).

¹⁸ Bennett and Checkel (2015b) identify 10 “Essential Best Practices” for good process tracing which are employed under a critical case design: “1. Cast the net widely for alternative explanations; 2. Be equally tough on the alternative explanations; 3. Consider the potential biases of evidentiary sources; 4. Take into account whether the case is most or least likely for alternative explanations; 5. Make a justifiable decision on when to start; 6. Be relentless in gathering diverse and relevant evidence, but make a justifiable decision on when to stop; 7. Combine process tracing with case comparisons when useful for the research goal and feasible; 8. Be open to inductive insights; 9. Use deduction to ask ‘if my explanation is true, what will be the specific process leading to the outcome?’; 10. Remember that conclusive process tracing is good, but not all good process tracing is conclusive” (260-1).

¹⁹ Chernoff summarizes perhaps the dominant definition or approach derived from Wendt’s *Social Theory*. Scientific realism is based on three core propositions: “First, the world is independent of the mind and language of individual observers. Second, mature scientific theories typically refer to this external world. And third, theories refer even when the entia to which they refer to are not directly observable. It is important to remember that [scientific realism] is a very specific doctrine about science, its theories, and its theoretical terms; it is not a general philosophical doctrine about the nature of knowledge or being” (Chernoff 2002, 192).

Given that the subject matter ultimately touches on many political and policy areas, data gathering on this case is conducted using a wide range of primary and secondary sources. Bennett and Checkel are instructive when recommending process tracers to “be relentless in gathering diverse and relevant evidence” and using Bayesian-inspired criteria and tests to contextualize the data (Bennett and Checkel 2015a, 27). Primary data employed herein includes archival research; textual analysis of trade negotiation documents; discourse analysis of case law and the language of judicial decisions; analysis of data retrieved from commercial databases; unpublished public statements made by policy makers; and, targeted interviews with officials. Considerable secondary source material is also leveraged. Where useful, these data are interpreted through the lens of Bayesian logical tests according to process tracing methodology.²⁰

Outline of Arguments and Chapters

By examining the implementation of international IP standards, this dissertation argues that institutional path dependence impacts negotiating positions and negotiating outcomes. Furthermore, the force and effect of the international standards are greatly impacted by domestic implementation. Where there is freedom of interpretation, policy choices will reflect historical realities. Market power arguments underrepresent the fact that trade agreements and international regulatory regimes arise out of domestic economic regulatory standards. They are historically cumulative in the sense that trade agreements increasingly contain embedded domestic regulations and are modeled after

²⁰ Logic tests include: hoop tests, smoking-gun tests, straw-in-the-wind tests, and doubly decisive tests (Bennett and Checkel 2015a).

past agreements. One set of standards arises from another.²¹ The pages that follow leverage historical institutionalism to demonstrate several interrelated institutional responses to the TRIPS/NAFTA regime. These feedbacks are not predicted by a market power theory. Each chapter briefly identifies what would be expected under market power then details how the perspective is falsified.

Chapter 2 provides a more detailed review of the relevant IPE literature. It argues that the study helps to address current gaps with respect to intellectual property protection, treaty implementation, and historical institutionalism in IPE. It explores various theoretical alternatives and discusses the tension between market power and historical institutionalism (HI). The chapter previews how the dissertation critiques market power while addressing one of the key criticisms of HI. It argues that “reinforcement” feedbacks are not the only empirical phenomenon that can support an HI approach.²² When rooted in domestic policy feedbacks, policy *resistance* and *repellence* also support the institutional perspective.

Chapter 3 considers *regulatory feedbacks* and the first chronological institution to directly result from trade related intellectual property reform: the quasi-judicial Patented Medicine Prices Review Board (PMPRB). Drawing on primary research and the policy literature, the chapter details the mitigating role and impact that this institution plays in Canada’s post-FTA pharmaceutical system as a unique price control mechanism specifically for patented products. In the context of TRIPS/NAFTA negotiation and implementation, it also shows how agreements tend to build on and accommodate

²¹ This proposition may seem obvious to trade negotiators who use the structure of past agreements to organize negotiations around issue chapters and spend considerable effort liaising with domestic interest groups regarding changes to domestic regulation. However, it is an idea that is under-reflected in IPE scholarship.

²² See discussion below.

existing institutions. The regulatory price control institution was formed in response to trade related intellectual property reforms and then was leveraged, protected, and strengthened as Canada's trade policy evolved through TRIPS implementation.

Chapter 4 argues that *regulatory feedbacks* were also important as Canada implemented US-style patent linkage provisions. Patent linkage is a key protection for IP owners and ties the regulatory approval of a generic medicine to the patent status of its reference brand (patented) medicine. Canada's patent linkage system was based on similar US provisions; however, these standards were only partially exported to Canada. This policy was significantly shaped to reflect local institutional and political realities. The chapter argues that Canada preserved domestic sovereignty by retaining flexibility to limit and reduce IP protections in the future. Indeed, Canada continues to modify these provisions as the international trade context evolves over time.

Chapter 5 considers *judicial feedbacks* and details the evolution of Canada's case law in the post-TRIPS era. Drawing on the legal literature and case-law discourse analysis, this section identifies institutional responses on the part of Canada's judicial branch to constrain the breadth of and definition of patentable utility under the so-called "promise utility doctrine." This is a legal test derived from common law institutions to invalidate patents granted by the Canadian Intellectual Property Office. The doctrine has gradually evolved to attach a more onerous standard for the demonstration of patentable utility in Canada, and thus produced international divergence on patentability outcomes. The standard has had the effect of invalidating patents for many lucrative and potentially lucrative products. It is a clear institutional response to companies pursuing advanced

patenting strategies in the post-TRIPS era. This issue has become the central focus of the USTR's Canadian IP advocacy, yet Canada is shown to have resisted this pressure.²³

Chapter 6 traces the emergence and assesses the impact of cost-constraining *procurement feedbacks* that act to limit the number and price of patented technologies funded by government. These technocratic procurement decision-making institutions were adopted by subnational governments to help limit public exposure—but not private market exposure—to the international IP regime (for a preview see Figure 6.7). This institutional layering essentially narrowed the practical scope of the international standards by screening out or creating conditions regarding public access to patented technologies. Academic ideas and institutions were adopted by the state and converted to provide cost-based technology assessment and decision making support. This has created a model for international diffusion of similar mitigating regimes at the *domestic* level in many countries. Canada was an international leader in this effort.²⁴ Norms and institutions diffused through international epistemic community cooperation and because there existed an established set of useful tools, not due to market power. Market power predicts that only large and powerful markets will determine regulatory standards, however, this is shown to be an incomplete perspective. Standards diffuse internationally through various mechanisms and for different reasons. HI layering and conversion is

²³ This resistance calls the universality and practical effectiveness of Sell's "naming and shaming" or blacklist causal mechanism is called into some question (Sell 2010, 780). Naming and shaming is a term that describes the mechanism of policy diffusion used by the US to encourage its trading partners to adopt and enforce higher IP standards. Naming and shaming is not always effective in Canada's case. Sell also identifies the "technical assistance" causal mechanism that may be relevant for the diffusion of standards to the developing world, but is less relevant for Canada.

²⁴ The mechanisms of policy diffusion reflect a much less formal and centralized version of international "best-practice" adoption where technocrats borrow select features from a "successful" system and graft them on to their own institutional structure (Slaughter 2004, 3-4, 11, 34).

critical to explaining regulatory implementation outcomes. See Figure 6.1 for a graphical overview of these arguments.

Throughout each chapter, the dissertation also shows *relational feedbacks* and traces how TRIPS standards are advanced and referenced in second-generation trade negotiations. Clear links are drawn between TRIPS implementation, Canadian institutional policy feedbacks, and the next generation of trade-related IP regulations whose IP measures are explicitly tied to TRIPS. For example, the Canada-EU Comprehensive Economic and Trade Agreement (CETA) was significantly shaped by a need to address legal issues created by NAFTA implementation. This history is important to capture and document as part of longer-term cause and longer-term effect relationships. Finally, Chapter 7 relates empirical process-tracing insights back to theory and concludes with some recommendations for further study.

Scholarly Contribution

The central scholarly contribution of this work is to identify how historical institutionalism matters even when overwhelming market-power dynamics are at play. It critiques and supplements the limited universe of causal mechanisms identified in the literature. As discussed above, it identifies and explains the significance of four distinct varieties of policy feedback that may be helpful as a framework to evaluate the implementation of other regimes and treaties. This work helps to address a key criticism of historical institutionalism identified in the literature relating to the concept of “repellence.” Repellence results when “actors respond to extant regulation by building up their own technical and institutional capabilities in order to develop a viable alternative to the hegemonic rules of the game” (Drezner 2010, 795). Critics of HI challenge the

temporal sequencing of institutional capacity by pointing to the possibility and existence of repulsion institutions (Ibid, 796). Here the argument is that path dependence would seem to predict that weaker regulatory actors will adopt and reinforce pre-existing standards: once the international regulatory die is cast it is difficult to transcend. The possibility of resistance and repulsion strategies undermines this parsimony and the temporal distribution of regulatory and technical capacity is thus less significant.

To the contrary, this dissertation shows that the existence of resistance and “repulsion”²⁵ can actually lend considerable *support* to an HI approach when the analysis is powered to do so.²⁶ When domestic institutions for a very small and dependent country such as Canada can resist and repel the standards of a dominant actor and even shape key elements of the international standard, then the case for historical institutionalism is much more powerful. Repulsion and resistance do not undermine the causal power of path dependence and sequencing when those responses are rooted in past domestic policy choices.

This argument leverages novel empirical research on the domestic implementation of intellectual property (IP) standards and the various institutions that mitigate the force of those international standards. The dissertation contributes new insights and practitioner perspectives gained through extensive archival research and interviews with officials. It presents a detailed historical chronology of negotiation and implementation processes specific to IP. It is also unique in drawing together diverse

²⁵ Here the term “repulsion” is not used exclusively as an “alternative” to the international regime, but rather as a mitigating institutional feedback that develops in parallel and acts to set the range of practical outcomes.

²⁶ The problem with the “sequencing of regulatory capacity” arguments to date typified by Ferrell and Newman (2010) is they are based largely on the EU providing a successful regulatory alternative to the US. The EU is itself a major market power and standard setter and thus a comparison with the US inherently has less explanatory leverage.

spheres of policy that are often treated discretely.²⁷ Regulatory, judicial, procurement, and relational policy feedbacks are examined herein as an integral part of the outcomes produced by the international intellectual property regime. Each is an essential part of the IP regime's distributional and normative outcome. Together they help to form a more complete answer to the question of how international regulatory regimes are designed and implemented.

Understanding the causal mechanics of Canada's implementation, compliance, and institutional response to international IP standards may have implications beyond this isolated case²⁸ and for other areas of international regulatory standard-making. If institutional resistance and repulsion are a fundamental part of international regulatory regime-making, this will have implications for both the international standard setting process as well as the prospects for successful rules-based cooperation in various areas of governance. Furthermore, regulatory challenges increasingly seem to be global in nature. It is thus important for IPE to pay more attention to the various ways in which global regulatory efforts intersect and interact with established local regulatory institutions.

²⁷ Inter-linkages are traced between trade diplomacy, domestic economic regulation, IP law, and even health care management. Each area is examined in considerable depth and practitioners across these fields should find empirical contributions beyond the theoretical IPE structure that binds them together.

²⁸ For example, despite considerably different institutional dynamics, China has adopted similar tactics to narrow the scope of IP protection through patent invalidations that are proving to be a considerable irritant in US-China relations compounding the perennial bilateral issue of IP enforcement. Inside U.S. Trade. 2014. "Following JCCT Pledge, China Shifts Reason For Invalidating Drug Patents" *Inside U.S. Trade* - 09/12/2014, Vol. 32, No. 36, Accessed September 11, 2014, <http://insidetrade.com/>.

Chapter 2 - Theorizing the Establishment of International Intellectual Property Rights Standards

The purpose of this chapter is to review the IPE literature on intellectual property (IP), the international IP regime, and regime formation more generally. It explores in greater depth the theoretical approach employed in the dissertation. It argues that there are three main gaps in the existing literature. These gaps are: 1) the relative dearth of consideration of intellectual property protection in core IPE debates despite its clear importance in contemporary global and local politics; 2) the gap in the literature regarding international trade and regulatory regimes where the regime's negotiation is typically the focus, with scant attention to domestic implementation; and 3) the gap in IPE, as compared to comparative politics, with respect to historical institutionalism. HI is only starting to attract more IR and IPE scholarship. After surveying the literature and discussing theoretical alternatives, historical institutionalism is argued to hold considerable promise as a lens to further investigate the evolution of trade and IP regulatory standards.

IPE and Intellectual Property

While IP protection and the promotion of R&D are widely discussed in legal, technocratic and economic policy literatures, these essential "knowledge-economy" related topics are comparatively understudied from an international political economy (IPE) perspective and are only beginning to be discussed in that literature. A search of top

IPE journals²⁹ for intellectual property, R&D, and related terms reveals that a small but growing number of IPE scholars have specialized in IP-related issues.³⁰

Even those who see the recent emergence of “global intellectual property politics” as a distinct area of study acknowledge the foundational role played by legal experts in shaping the trajectory of analysis. Recent scholarship has been framed either in binary oppositional terms or inordinately focused on the “legal standard” as the dependent variable with little attention to “preferences, behaviors, practices, principles or worldviews related to IP” (Morin et al. 2011, 93). In other words, there is considerable study of IP, but IPE perspectives and the “social processes that lay behind laws” are just beginning to emerge (Haunss and Shadlen 2009, 2). Scholarship from non-IPE journals such as *Intellectual Property Journal*, *WIPO Journal*, *Journal of World Intellectual Property*, or *International Journal of Intellectual Property Management* has framed this work along technical rather than political or systemic lines of inquiry.

Clearly there are many critical and normative perspectives on IP; however, these perspectives have not generally played a role in major IPE debates. References seem *ad hoc* with few clear and sustained research programs. This is surprising for a number of reasons: the comparably high volume of work on IP in related disciplines of law and

²⁹ *Review of International Political Economy; International Organization; International Studies Quarterly; Millennium; World Politics; Global Governance.*

³⁰ These include Susan Sell, Christopher May, Christian Zeller, David Tyfield, Jean-Frédéric Morin, Kenneth Shadlen, Duncan Matthews and Viviana Munoz-Tellez, and a few others. IP is studied or cited as: 1) a rent-seeking instrument imposed on powerless nations by powerful ones (Sell 2003, Sell 2010; Zeller 2008); 2) the product of competition between global capital and global civil society or between industry sectors (Sell and Prakash 2004); 3) a barrier to the poor accessing medicines under a consolidation of international standards (Shadlen et al. 2011; Keohane 2011); 4) an ineffective departure from the historical function of property rights (May 2010; Sell and May 2001; 2006); 5) an imperfect vehicle for policy learning between advanced and developing economies (Matthews and Munoz-Tellez, 2006); 6) the handmaiden of “financialization” under the monetarist revolution (Tyfield 2008); 7) the object of academic-NGO resistance and cooperation (Morin 2014); and, 8) as a key competency of select international organizations (IOs), namely the WTO and the World Intellectual Property Organization (WIPO), which scholars are interested in as empirical cases of international regime formation (Sell 2010; Muzaka 2013a).

economics; IP's clear importance as a distributional policy, both domestically and internationally; the occurrence of major real-world political contests over IP; the centrality of IP to new sources of wealth and the knowledge economy; the increasing importance of IP in trade negotiations and regimes; and, particularly the centrality of IP to the trade diplomacy of major powers.

The most IPE-centric work has used IP and IP-intensive industrial sectors as lenses for understanding the formation of international regulatory regimes focusing on the multilateral Trade Related Aspects of Intellectual Property Protection (TRIPS) agreement. Notably, Susan Sell has employed an historical institutionalist approach to identify the US domestic political sources of TRIPS. According to Sell, the consequences of TRIPS include "profound and costly domestic institutional changes," where "international market regulation has increasingly penetrated domestic regulatory environments in ways that compromise domestic political bargains" (Sell 2010, 735-6). Sell is particularly focused on the domestic institutional sources of US policy: how IP diplomacy became such a priority for the US and the coalitions that formed around a powerful and IP-focused US Trade Representative.

While IP has traditionally been viewed as a fairly technical and legal subject, its emergence as a major component of the global trade regime has caused a few IPE scholars to take notice and examine its proliferation in greater detail. This scrutiny has drawn out important issues related to social equity and North-South power dynamics. However, the oppositional undercurrents informing this work seem to have produced a fairly narrow set of identified causal dynamics related to policy diffusion that in some ways may *exaggerate* the power of the US to monopolize policy outcomes. In actuality,

there has been very little study of outcomes that are realized at the domestic institutional level following international standard setting. There is clearly a need for more work on the causal dynamics of the international IP regime, specifically, the mechanisms related to regime *implementation*. The handful of edited volumes, books and articles on implementation have considered overt political opposition and coalition building as a source of resistance (Krikorian 2009); issues of asymmetrical political mobilization (Shadlen 2009); and have focused almost exclusively on the developing world finding considerable cross-national variations in outcomes (Deere 2009; Krikorian 2009; Shadlen 2009).

Other work has considered policy implementation prospectively and focused on the outlook and strategy regarding the recent World Intellectual Property Organization (WIPO) development agenda (De Beer 2009). In the first comprehensive political examination of TRIPS implementation focusing on developing countries, Deere (2009) identifies considerable cross-national variation of implementation outcomes. This variation “defies parsimonious explanation” but seems to be rooted in intense and complex post-TRIPS political contestation with differing technical capacity and TRIPS negotiation experience playing a determinative role (Deere 2009, 2, 20-23). Thus even if this is not explicitly an historical institutionalist account, it is one with considerable institutional and sequencing undercurrents. More specificity on the role of historical institutionalism and IP regime implementation could enhance and clarify these provisional insights on implementation.

With respect to standard-maker to standard-taker diffusion, Sell identifies two mechanisms: the “naming and shaming” or blacklisting mechanism employed by the

USTR and the “technical assistance” mechanism that is a prominent feature of the WTO TRIPS regime (Sell 2010, 782). The US Trade Representative uses the Special 301 list of IP offender nations to “name and shame” other countries into compliance with its norms. Alternatively, technical norms are injected directly into the policy regimes of less developed countries via the WTO’s technical assistance programs. This focus is characteristic of the cursory work to date on the international IP regime. Scholars across theoretical perspectives have typically focused on mechanisms of diffusion—from standard-maker to standard-taker—and have not robustly explored potential feedback mechanisms in the opposite direction. They have not sufficiently addressed the impact of the standard-taker’s institutional history. As such, there is a gap in the IPE literature on the extent and severity of domestic institutional changes, the impacts of institutional layering, and importantly, any policy feedback in effect as a given set of international standards evolves over time (see Thelen 2003, 233). This is particularly important as it relates to a regime’s effectiveness in shaping domestic institutional structures, given that a realist argument would suggest that existing institutions of the standard-taker should not have much determinacy independent of power. However, implementation feedbacks can powerfully shape the net impact of the regime and are relevant as standards evolve over time.

Explaining International Intellectual Property Regulation

The IPE literature on the creation of international IP standards has focused almost exclusively on the role of US power, corporate interests, and the formation of domestic interest coalitions around the USTR (Sell 2010; 2003). This instrument of executive-branch power has driven the globalization of US norms (Ibid). Even where norm

formation is framed as an act of socialization—an exercise of soft power or attractiveness—a hegemonic US is framed as a primary driver (Morin et al. 2011, 95). Undergirding many of these accounts are implicit assumptions regarding business interests, associations and lobbyists and their influence within the US political system.

The key determinant of the international IP standards and enforcement regime is framed by Sell (2009) as the result of an asymmetrical “Cat and Mouse” power competition between pro-IP business groups (the Cat) and anti-IP civil society groups (the Mice), who respectively promote or resist American IP policy (Sell 2009). The idea that the Cat shops for fora to articulate and enforce its interest helps to paint a disjointed and somewhat *ad hoc* picture of the sources of international standards. Putting aside the predatory and power asymmetry assumptions inherent in the metaphor, the very existence of international IP standards suggests that the Cat has won or is winning the international contest. More fundamentally, the analytical focus on standard-maker forum shopping *itself* would tend to undermine the general argument that institutions can matter and be determinative of outcomes. If the institution is simply a transient venue for interest articulation between competitors who are unequally endowed with power, then institutions and institutional development over time cannot really be attributed meaningful roles. However, the study of comparative and American politics suggests that institutions do matter. They are tenacious and have an impact on many different political outcomes. So unless institutions only matter at a domestic level, then some reconciliation of power and institutions at the international level is warranted. As argued

herein, domestic institutions and politics can also have impact at the international level (see also Katzenstein 1978, 4, 5, 11; Evans et al. 1993).³¹

There are a fairly limited number of causal mechanisms identified in the literature that help to explain international intellectual property rights and the diffusion of international regulatory standards. There is also a lack of precision about what matters. Rejecting strict rational choice and liberal efficiency-based approaches, Sell weaves a complex tapestry of structural factors such as the global ‘march of capitalism’ with agent-centric arguments such as lobby groups optimally organized to exploit national politics (Sell 2003, 4-6). US institutions are framed by Sell as the fabric that stitches these structural and agent-based accounts together in that structures and agents mutually influence institutions, both shaping and being shaped by them (Ibid, 7). The structure-agent-institution complex is a difficult one to unpack and leaves the observer wondering if *everything* really matters (international power structures, capitalism, individual agents, coalitions of agents, US state power, US corporate power, institutions, history, culture) all at once? The legacy of the agent-structure debate in international relations (IR) is to highlight important meta-theoretical issues while criticizing ontological reductionism (Wendt 1987, 342). But it also has contributed to a proliferation of causes rather than providing clarity and precision on the sources of international IP standards.

Others scholars have argued that there are broader, problematic, discursive issues at play and make a normative case for decoupling the concepts of competitiveness, innovation, and IP rights (Muzaka 2014b, 838). But how these discursive and socialization factors compare vis-à-vis power and market size is not always clear. For

³¹ Katzenstein (1978) argues that role of domestic ‘structures’ and domestic politics in international political economy is higher during periods of hegemonic decline and that systematic analysis of domestic structures is necessary to understand IPE (5,11).

example, does European Commission naming and shaming via the designation of those ‘priority countries’ infringing European IP really matter given the absence of actual sanctions with the force of the EU market behind it (Muzaka 2013b, 837)? Consider a hypothetical case where a domestic IP policy change occurs in a mid-sized power (*State A*) following naming and shaming by both the EU and a smaller market (*State B*) that has a closer trade relationship with *State A* than the EU. Without an accompanying theory of market power, or a detailed account that traces clear causal mechanisms linking cause and effect, we have no way of knowing the source of the policy change. It could be the result of EU pressure, *State B* pressure, some other *State A* factor such as domestic producer interests, or 30 years of normative socialization linking IP rights to innovation and competitiveness.

There is an ongoing gap in the literature regarding the sources, and especially the practical evolution, of the international IP system. It is clear that US power and the power of corporate actors play important roles. But to gauge the extent of that role, it is important to track the manifestations and competencies of US power and how it may extend into the local politics and regulation of those nations who are subject to it. In other words, how encompassing and effective is US power to achieve its IP objectives? It is proposed that because power is inherently relational, we must look to other polities to trace this and not look solely at *co-constitution* of policy agents and political structures in the US political system (Sell 2010). For example, Sell looks at the co-constitution of the USTR and the IP lobby and the mechanisms used to advance IP interests. However, she does not robustly address the *relational* dynamic of standard-taker implementation tactics.

Some legal scholars have looked at the issue of international IP standards from a holistic perspective where local realities and institutions are more comprehensively accounted for as part of the outcome variable. While critical of US power and the political influence of US industry, one research program has stopped well short of exaggerating that power by looking closely at institutional resilience. Helfer and Alter (2014) examine the Andean Tribunal of Justice (ATJ) a regional supranational judicial body in western South America. Its docket has come to be dominated by pharmaceutical intellectual property matters. The authors argue that despite struggling from many political challenges, the Andean integration effort has emerged as an institutional forum for actors to push back against US IP demands (Helfer and Alter, 2014, 256). The problem with views privileging the role of global capital in setting international IP standards is that they obfuscate these local sources of power and the very real heterogeneity that results in the application of a given international agreement. Over-determinism of power asymmetry precludes the possibility of resistance and repulsion.

It is true that as an American-driven regime, TRIPS is skewed to towards American interests and there is no denying the role of corporate power in the US political system. Equally, however, it is important not to overstate the ubiquity of the international regime and its capability to set foreign standards at the local level. Even the most hardened critics of the US pharmaceutical industry argue that TRIPS by no means entails the type of power and standards ubiquity that some Marxists and others simultaneously overstate to make a normative case against increased IP protection:

TRIPS does not impose uniform law in any manner or shape. It established barely harmonized international minimum standards of protection that, in the absence of any Agreed Statement or official Acts, WTO members continue to apply differently...The hard truth that Big

Pharma cannot swallow is that U.S. patent law did not become global law under TRIPS, and that the United States cannot prescribe universal patent standards for the rest of the world any more than France could prescribe uniform patent law in 1883 when the Paris Convention was first adopted (Reichman, 2014, 3-4).

This is not to say that TRIPS is not the primary set of standards comprising the international regime or a useful tool for US multinationals: it is both. The key point is that an international intellectual property regime cannot be conceptualized as one monolithic international agreement such as TRIPS but rather the practical intersection of international and local institutional standards. US power is significant but has not enabled the transcendence of local political and institutional realities. Rational, liberal, and Marxist perspectives have yet to address the fact that different regulatory standards can emerge from one international agreement due to various domestic institutional realities. This lack of attention to domestic institutions produces somewhat distorted accounts of international IP regulation and a clear gap in the literature.

Explaining Regime Creation and Regime Complexes

There is no shortage of consideration in IR and IPE on the topic of international regimes. The study of regimes played a central role in international relations theory in the 1970s and 1980s and has been revitalized more recently in the IPE literature on international regulatory regimes and regime complexes. With a few notable exceptions in the area of environmental regimes,³² the trend observed for IP regimes regarding a relative dearth of implementation literature reflects a broader gap in the regime literature. Theorizing on international regimes has evolved from its early and now familiar articulations, to be dominated by the study of network analysis and inter-regime interaction effects of the

³² See below Rosendal 2001; Oberthür and Gehring 2011; Gomar et al. 2014; Raustiala 1997.

burgeoning “regime complexes” literature (Young 1980; Krasner 1982; Raustiala and Victor 2004; Alter and Meunier 2009; Orsini et al. 2013).³³

Definitions of regimes typically employ the concept of “expectation convergence” between parties, where *predictability* is seen as a precondition for successful cooperation. Regimes are also treated as a subset or somewhat synonymously with international “institutions.” Young defined regimes as such:

Regimes are social institutions governing the actions of those interested in specifiable activities (or meaningful sets of activities). As such, they are recognized patterns of practice around which expectations converge. It follows that regimes are social structures. It is important not to mistake them for functions, though the operation of regimes frequently contributes to the fulfillment of certain functions (Young 1980, 332).

Here Young differentiates between an international issue regime and its functional manifestation. The extent to which a regime is codified is another element given that ‘recognized patterns of practice’ could involve a formal agreement or simply be an accepted social practice. This fairly broad definition may be applicable to general social institutions such as “intellectual property” but would seem less useful for describing when common *rules* are established to encourage predictable behavior and cooperation.

In an alternative definition that is widely cited, Krasner brings the state actor and the mechanics of the regime into sharper relief: “sets of implicit or explicit principles, norms, rules, and decision-making procedures around which actor expectations converge in a given issue-area” (Krasner 1982, 186). Krasner’s articulation introduces concepts that would endow those actors with normative ‘rights or obligations’ as well as behavior

³³ The term “complexity” is used herein, generally, in the context of a proliferation of regimes as an independent variable, per Alter and Meunier (2009) on “The politics of international regime complexity.” Conversely, the term “regime complex” is used more in its context as a dependent variable. For example, per Keohane and Victor’s (2011) question of what explains the existence of “a loosely-coupled set of specific regimes” in a given issue area.

rules and specific mechanisms of cooperative decision-making. This is more consistent with contemporary notions of trade regimes, enforcement provisions and specific rules with respect to intellectual property protection or other regulatory standards.

Explanations for regimes have traditionally been grouped into four non-mutually exclusive categories: Structural, game-theoretic, functional, and cognitive (Haggard and Simmons 1987, 502). More contemporary debates in IPE have taken a slightly different theoretical approach: reframing structuralism in terms of market power and the capacity to compel (Drezner 2007); neoliberal institutionalism (Keohane and Nye 1977; Keohane 1984) which privileges the costs and benefits of cooperation under a rational actor model and melds earlier functionalism and neofunctionalism (Haas 1964) with rational choice (Olson 1965); constructivism (Ruggie 1982; Onuf 1989; Reus-Smit 1997; Wendt 1999) which stresses norms and identities; and historical institutionalism, a framework which stresses institutional processes, policy feedbacks and sequencing of regulatory capacity development and leverages *different* theoretical perspectives (Farrell and Newman 2010).

Structuralism / Neorealism – The Supply Side

Like the work on the internationalization of US IP standards, the various explanations for the emergence of regimes often focus on the centrality of a hegemon to facilitate international agreement. Haggard and Simmons note that structural interpretations of hegemony and hegemonic stability are “not always clear about what hegemons actually *do* to promulgate and maintain a given set of rules” (Haggard and Simmons 1987, 502). Neorealist accounts stress market size as a primary independent variable (Lütz 2011, iv). Scholars *have* given greater weight and consideration to the incentives of regime-takers by shifting focus from large international organizations (IOs) themselves to consider the

specific regulatory functions that IOs perform including capital market regulation, trade regulation, health and safety, intellectual property and other issues. However, the critical role of the dominant market has largely been upheld, for example, when explaining the process of regulatory innovation (Simmons 2001, 615).

One problem with purely structural or neorealist accounts of international regulatory regimes is that it is not fully clear what will happen in multi-polar systems where there may be competing standards from major market powers. Bilateral regulatory cooperation can become extremely challenging even between close economic allies such as the US and EU (Lütz 2011, iv, xv). Structural explanations also typically reject domestic institutional sources of policy, neglect institutional factors impacting the ability to *leverage* market power internationally, and neglect different paths of institutional evolution (Bach and Newman 2010; Farrell and Newman 2010, 614).

There is compelling evidence in support of the argument that domestic regulatory institutions and regulatory capacity³⁴ help to shape international market regulations (Bach and Newman 2010, 667) thus calling strictly structural accounts into question. To fully understand the regime other factors may also be needed such as functional and technical capacity—how well a given set of national standards achieves its objectives and how replicable it may be in different national contexts. While regime supply and market power cannot be fully dismissed, the “unfulfilled” challenge has been in finding room between causal perspectives as part an integrative framework that can combine “insights from different social-theoretical toolkits” (Checkel, 2015 75).

³⁴ Regulatory capacity is an umbrella term used by Bach and Newman (2010) to encompass “regulatory expertise, the coherence of regulations, and the extent of the regulator’s sanction authority” for example the “power to exclude from the domestic market” in situations of non-compliance (671).

Neoliberal Institutionalism – The Demand Side

The regimes literature of the 1980s and 1990s was primarily interested in the core IR question of whether cooperation is possible under international anarchy (Keohane and Nye 1977; Krasner 1982; Keohane 1982; 1984). It focused on how cooperation can emerge and how institutions may sustain cooperation in the event of hegemonic withdrawal or decline (Keohane 1984, 49, 135, 245-7). An important component of this was the role of international organizations (IOs) in setting international agendas and providing the forum for coalition formation (Keohane and Nye 1977, chapter 2-3). There are some important differences in the various strains of liberal and functionalist thinking in IR³⁵ and even disagreement on whether neoliberal regime theory is fundamentally *liberal*. However, in general terms neoliberal institutionalism explains international institutions as the product of a rational calculation of the costs and returns of collaboration, where institutions help to facilitate cooperation (Moravcsik 1997, 536; Greco 1988, 487).

Neoliberal institutionalists stress the importance of reducing transaction costs, but as with earlier functional and neofunctional theories, suffer from the central explanatory flaw that “they are better at specifying when regimes will be demanded rather than suggesting how or when they will be supplied” (Haggard and Simmons 1987, 506). Furthermore, neoliberal institutionalism provides no clear guidance on which issue areas will be most likely to produce formal institutions (Ibid, 508). The core assumption is one of efficiency where the institutional form is determined by relative costs or the friction created by varying national regulatory approaches (Bach and Newman 2010, 670, 675).

³⁵ See Greco (1988) for a detailed account and critique.

Liberal institutionalism owes debts to both the functionalist literature but also to neorealism in so far as it is a response to supply-side structuralism (i.e. hegemonic stability theory) and is explicitly a demand-side correction to it (Keohane 1982, 326). In examining the demand-side economics of regimes, the prospect for nuances between regimes emerges based on their function: cooperative or simply “insurance” against uncertainty. While there is an enormous diversity of regimes, they most typically aim to provide predictability through behavior “controls” rather than in the capacity of providing collective insurance against risk (Ibid, 351). These demand-side nuances may help to explain some instances of cooperation but the natural impulse of rational actors is often to shirk on responsibilities when there is latitude to do so. Thus, the image of cooperation that emerges from the rational-choice informed liberal institutionalism literature is that it is possible, difficult, and will only occur if transaction-cost friction can be substantially reduced to make cooperation worthwhile.

Most regulatory regimes would likely fall into the category of control regimes. The intellectual property regime is clearly an attempt to create property certainty for innovators who produce intangible property. But from the perspective of non-IP producing nations, it is not a mutual problem in search of an efficient solution, but rather more closely resembles a rent-extracting apparatus. Given that only one party, the IP producer, actually has demand for the regime, issue linkage is absolutely critical to the regime’s existence. For example, IP is linked to trade which non-IP producers may have a much higher demand for. As such, in the case of IP it is easy to see why there is often a default to more structural accounts and those from various perspectives stressing US hegemony: The hegemon is the party demanding IP and the existence of an IP regime

suggests that its power was leveraged effectively. It is surprising, however, that many critics of IP policy and even some liberal free-trade advocates are *themselves surprised* by the insertion of TRIPS into the Uruguay Round, and neglect to recognize the inherent *quid pro quo*. After all, trade negotiators often link and horse-trade market access in one sector for trade barrier concessions in completely unrelated sectors. Negotiating positions and concessions are contingent on many different domestic factors and priorities.

In many cases of international cooperation and regulatory harmonization, there are empirically supported neoliberal/functional arguments to be made about parties wanting to harmonize clashing standards and examples of regimes that facilitate cooperation. The functional parsimony of neoliberalism, however, largely precludes domestic sources of policy and neglects how local social preferences are translated into international cooperative efforts. Reflecting on theoretical progress of the approach, its proponents acknowledge that for “international relations theory to make really significant progress it will need to go beyond institutional theory’s analysis of institutional strategies to explain variation in state preferences” by building on *domestic* institutions theory or on social construction (Keohane and Martin 2003, 96).

Some accounts have sought to differentiate a distinct *liberal* approach emphasizing social preferences and state-society relations (Moravcsik 1997, 515). Such a differentiation, however, cannot save liberal accounts from the criticism leveled by constructivists that both neorealism and (neo)liberalism fail “to explain institutional forms that endure shifts in the balance of power and [are] contradicted by the emergence of different fundamental institutions under similar structural conditions” (Reus-Smit 1997, 556). This insight begs the analysis and evaluation of international institutions over

a longer timeframe, which is the aim of many historical institutionalists (e.g. Pierson 2004). However, macro-social analysis of fundamental institutions such as property rights is a much taller order than evaluating the emergence of a specific set of IP rules or regimes that are closer to contemporary policy debates regarding international regulatory cooperation. The liberal perspective could be subject to the same criticism leveled against structuralists: many different organizational forms may emerge under the same “constitutional structures” and “fundamental institutions”³⁶ (as defined by Reus-Smit 1997). As such, a theory with closer connections to the policy-making process and domestic policy institutions seems warranted.

Constructivism

Keohane and Martin’s (2003) call for domestic factors and social construction as the next step in the evolution of institutional theory is in some ways advanced by Judith Kelly’s 2004 *Ethnic Politics in Europe*, which introduces analytical balance between rational incentives and ideational norms. Checkel notes that Kelly was among the first to consider domestic implementation dynamics with policy outcomes (Checkel 2015, 83). He argues the central contribution of this constructivist work is to argue that international organizations “matter” and “shape state behavior only when they work through the domestic politics of particular countries” (Ibid). Probing domestic implementation dynamics as a central component of policy outcomes is a primary objective of this dissertation. While looking at a different policy area, the rational and constructivist causal

³⁶ As defined by Reus-Smit, fundamental institutions are “deeper institutional practices that structure modern international society” such as contractual international law and multilateralism. “They are ‘generic’ structural elements of international societies” which transcend “changes in the balance of power and the configuration of interests, even if their density and efficacy vary” (Reus-Smit 1997, 555).

mechanisms uncovered by Kelly's process tracing are highly symmetrical with Sell's (2010) naming and shaming mechanism for IP. These mechanisms do not *necessarily* need to have strong associated sanctioning penalties to be an effective constrainer of action. "Normative pressure" as the constructivist causal mechanism in Kelly's account is similar in that "external actors do not link any concrete incentives to behavior but rely solely on the use of norms to persuade, shame, or praise actors into changing their policies" (Kelly 2004, 8). While similar, it should be noted that Sell's mechanism is actually backed up with market power in the form of sanctions for those cases deemed by the USTR to be particularly deviant from the codified norm.

The constructivist perspective on international institutions is more nuanced than neoliberal cost-benefit explanations due to its focus on primary social institutions, state identity, and the corresponding impact on institutional practices (Reus-Smit 1997, 563). In the earlier regimes debate, constructivists depicted regime formation and evolution as the "concrete manifestation of the internationalization of political authority" or the willingness to submit to the cooperative systems (Ruggie 1982, 380). Under "embedded liberalism"—the American-led post-war manifestation of liberalism distinct from earlier *laissez faire* incarnations under *Pax Britannica*—the willingness to submit to the costs of multilateral cooperation is facilitated by compromise: an accompanying flexibility to mute its impacts through domestic Keynesian fiscal policy (Ruggie 1982, 393).

Following this specific account we might view the adoption of IP standards into the existing trade regime as an example of "norm-governed change" or "adaptive restorations of prior sets of norms" (Ruggie 1982, 384). This would entail an economic liberalism that extends property rights to the domain of knowledge. Conversely, however,

some argue that the internationalization of IP rights fundamentally alters domestic social bargains (Sell 2010). As such, it could also be argued that the IP regime marks a *departure* from the *embedded liberal* bargain. This would depend on the empirical magnitude of the departure from embedded liberalism, for example, the extent of changes to domestic policy required to comply with the international regime. This varies greatly across space and time.

Similarly, the “constructivist institutionalism” thesis that identities can trump material concerns in international decision-making is surely correct in certain situations (Schimmelfennig 2003). Outcomes, however, will likely be contingent on the magnitude of the costs and the centrality of identities. For IP, it might be argued that exceptions to the regime such as the Global Access to Medicines Initiative are an example of norms and identities trumping material considerations. For example, US enforcement of its material interest (higher international drug prices) is trumped by norms of fairness, progress in human health, and the US self-identity as a liberal society and a non-predatory force for good in the world. Critics, however, will be quick to point out that the power of this identity has its limits.

Constructivist work of the mid-1990s emphasized the role of socially constructed knowledge and the causal role of norms, values and associated state identities in shaping world politics (Finnemore 1996; Jepperson et. al 1996; Onuf 1989; Wendt 1999). Finnemore shows that international institutions are socially constructed and that international organizations including the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Red Cross, and the World Bank “socialize states to accept new political goals and new values that have lasting impacts” on IPE and state

structures (Finnemore 1996, 3). This is operationalized via moral principles (Red Cross), persuasion (UNESCO), or coercion (World Bank) (Ibid, 22). Where Finnemore's account is innovative in refocusing agency from the state to IOs and conceptualizing norms as social structure, Checkel points out that her account is weak on domestic politics, lacks clarity on the co-constitution of agent and structure, and does not explain asymmetrical norm diffusion (Checkel 1998, 332).

To this critique it should be added that the creation of a domestic science policy and bureaucracy—whether or not informed by global norms propagated by UNESCO—presumably has only limited distributional and normative impact on the *body politic* and state identity. A host of more central factors such as history and culture likely shapes this. The rapid proliferation of science policy in many countries is interesting and intuitively points to a structural cause as opposed to a domestic one. However, there are perhaps other more interesting structural factors associated with this policy outcome, such as the material and labour impacts of globalization and its normative discourse. It seems likely that UNESCO's 'persuasion' may have only been the most immediate catalyst for policy change and other factors are also at play. Applied to intellectual property, the most relevant comparator for the role of UNESCO in socialization is not an international organization but a state actor, the USTR. The USTR was socialized to the desirability of IP by the US corporate IP Lobby and jointly advances its argument frames (Sell and Prakash 2004, 156). While the WTO has a bureaucracy, the US executive branch is the central enforcer of TRIPS and proposes TRIPS modernization through regional trade agreements.

Part of the problem with constructivism is its intuitive success—of course norms and identities matter just as material power matters in shaping political outcomes at different levels. However, given that socialization and norm formation have many sources and context-dependent impacts it is difficult to differentiate signal from noise. For example, IP norms become entrenched due to USTR advocacy (Sell 2010). Sub-state linkages such as between developing state leaders and IP legal experts drive the export of US norms (Morin et al. 2011). There may also be socialization-counterweights from academics and non-governmental organizations (NGOs) who now have new and incredibly powerful norm-shaping communications tools in the Internet era (Morin 2014). In the global discursive competition the question often becomes: whose norms (Sell and Prakash 2004)? In other words, to explain why some norm-makers are influential and others are not, we must consider other potential factors such as material power, entrenched institutions, or communication tactics.

Regime Complexes

The proliferation and frequent overlapping of regimes has recently led scholars to look at regime interaction effects. The more intricate and interactional image of international regimes in the regime complex literature considers the politicization of regime implementation as one of several dependent variables explained by international regime complexity (Alter and Meunier 2009, 16; Hafner-Burton 2009, 33, 35). Like the work on IP, scholarship in the area of trade and human rights has stressed the heterogeneity and specificity of domestic outcomes as well as the political jockeying that helps to explain diverging outcomes through such mechanisms as forum shopping (Hafner-Burton 2009,

36). Diverging domestic outcomes are explained not by local *institutional experience* but in terms of international regime complexity.

These outside-in dynamics of regime complexity shaping the local range of options and cross-national variation are apparently also relevant to intellectual property. At times regime complexity provides domestic governments with room to maneuver, but complexity also “provides opportunities for powerful states to narrow the options available to weaker countries to implement intellectual property rules into their national legal systems” (Helfer 2009, 42-43). In other words, regime complexity provides forum shopping opportunities for both regime-maker and regime-taker. Intuitively, this proliferation and complexity may favour powerful nations (Drezner 2009, 66). However, this apt insight from Drezner is clearly aimed at transnational regime-setting capabilities. It is likely true that great powers (and highly organized actors such as transnational corporations) are in a better position to establish regimes, enforce rules and secure favorable outcomes in the international market and its various fora. However, this view is incomplete. What if a weaker power turns to its own domestic institutional apparatus as the chosen “forum” to secure favorable outcomes? Here the great power may not have significant expertise or proximity to rule-making, and may not fully appreciate institutional dynamics required to secure the outcomes it is looking for. It is hard to know the extent to which Helfer (2009) is correct regarding the ability of powerful nations to limit the range of implementation options. There simply has not been enough study of implementation outcomes and associated causal mechanisms.

The present analysis may help to fill the gap. Canada and other smaller powers are not typically in a position to establish new international fora to provide an alternative

to TRIPS or many other issue regimes. However, there are many institutional corrections and feedbacks evident as part of the implementation process. By focusing increasingly on international complexity across the spectrum of regimes, scholars may be missing *local complexity* and the “implementation clash” between international standards and domestic institutions.

There are a few examples of regime implementation that should be noted. For environmental regimes, this is clearly an area of considerable concern. Scholars have studied the successes and failures of countries to implement standards within the context of overlapping international regimes and have identified implementation *coordination* as a challenge (Gomar et al. 2014, 127; Rosendal 2001, 96; Oberthür and Gehring 2011, 27). An earlier generation of work on environmental regime implementation also showed the impact of domestic politics and institutions and specifically the *anticipation* of a regime’s impact as complicating factors to its success (Raustiala 1997, 482). Others have identified variables such as stakeholder participation and the state of economic transition as determinates of implementation (Victor et al 1998, 306, 312).

Scholars have also looked at standards compliance and non-compliance within the Euro-zone as an example of ‘regime’ implementation focusing on the interaction of enforcement and management strategies (Tallberg 2002, 624-5, 637). Excluding these and perhaps a few other pockets of work, it is fair to say that the dominant discourses on international trade and finance regimes have not been similarly scrutinized. The trade regime complex literature has produced some interesting insights with respect to enforcement and compliance, for example litigant forum shopping between dispute settlement fora such as the WTO and NAFTA (Davis 2009, 28). However, domestic

institutional responses are not robustly considered. Furthermore, there is no consensus on the positive or negative impacts of regime proliferation.

Like Drezner, this analysis is somewhat skeptical of the causality of regime complexity itself, independent of power and interests. However, diverging from Drezner, this analysis adopts the perspective that regime complexity should not be considered independent of institutional history. The regime complexity literature is largely agnostic on this point. It overstates the causal power of international regime complexity and understates domestic complexity and interests related to implementation. In highlighting the prospect for institutional forum shopping, this work in some ways degrades the essence and importance of domestic institutions and the associated political context from which they arise. One idea is to introduce these factors into complexity analysis. “Non-regime” theory predicts that “historically embedded conceptions” of economic rights and domestic politics prevent some economic regimes from emerging (Dimitrov et al. 2007, 253). It should follow that historically embedded conceptions of economic rights and domestic politics also play some role in the *maintenance* of incumbent domestic institutions.

Historical institutionalism needs to better account for the impacts of forum shopping (Drezner 2010). However, it is equally true that those adhering to a *regime complexity* hypothesis should consider institutional history as a significant influencer or modifier of capacity and thus a potential indicator of where regime complexity will matter, and where it will not. For example, while not examined herein, it is plausible that international regime complexity will be less significant when there exists a strong and historically or politically rooted domestic institution in a given governance area.

Institutional feedbacks clearly require further study. The regimes literature has contributed several interesting innovations including the examination of path dependence of international regimes—the impact of norms as reinforced by existing global institutions (Zelli et al. 2013, 113; Orsini et al. 2013, 37). However, this is not an intuitive fit with regime complexity as a strong independent variable. Reaching back into the domestic sphere for other sources of path dependence and feedback is perhaps just as important. This is a central task and contribution of the present dissertation.

Liberal Pluralism and Two-level Games

As discussed in the sections above, dominant international relations theories are poorly suited to accounting for domestic political factors, and it is often the express purpose of those theories not to (Waltz 1979, 121-2). This is challenging because we see daily occurrences of domestic factors impacting international outcomes despite the need to abstract and compartmentalize domestic and international domains for theory-building purposes. International institutions, defined narrowly as explicit negotiated arrangements, or those that are rationally “designed,” do not exist in a vacuum: they reflect the priorities of their sponsors (Koremenos, Lipson and Snidal 2001, 762). As such, even under rational choice approaches it may be necessary to “relax the unitary actor assumption to incorporate key domestic political factors” to explain institutional design from a “forward-looking” perspective (Ibid, 797).

Perhaps the most accepted approach in the literature remains the “two-level game” framework, which treats domestic and international games separately but argues

both are essential considerations for policy makers (Putnam 1988, 434; Lütz 2011, xiii).³⁷ More generally, the pluralist “domestic sources” approach typified by two central volumes (Katzenstein (1978) and Evans et al. (1993)) has recently been revisited in the transatlantic-relations sub-set of the international regulation literature (Lütz 2011; Eimer and Philipps, 2011). The Evans volume pays careful attention to the domestic influences on international bargaining and takes an “integrative approach” to analysis. It argues that “international bargains are not simply about relations between nations [but] are also about the distribution of costs and benefits among domestic groups and about domestic opinion divided on the best way of relating to the external environment” (Evans 1993, 397). For example, one interesting comparison of developing countries’ structural adjustment negotiations with the International Monetary Fund (IMF), demonstrates leaders’ bifurcated (domestic and international) decision-making processes (Kahler 1993, 337, 388-9). This work highlights the importance of domestic institutions and the domestic political calculation of “win sets” in accounting for differential implementation outcomes (Ibid).

Similarly, Katzenstein’s research program on domestic structures in the late 1970s “petered out” in IR but was more robustly addressed in comparative politics and historical institutionalism (Ferrell and Newman 2010, 610-11). This work explored how domestic capacities could be determinative internationally. The account offered a compelling critique of the popular bureaucratic bargaining model arguing that it did not

³⁷ Putnam defines the two-level game: “At the national level, domestic groups pursue their interests by pressuring the government to adopt favorable policies, and politicians seek power by constructing coalitions among those groups. At the international level, national governments seek to maximize their own ability to satisfy domestic pressures, while minimizing the adverse consequences of foreign developments. Neither of the two games can be ignored by central decision-makers, so long as their countries remain interdependent, yet sovereign” (Putnam 1988, 434).

sufficiently employ theoretical abstraction and overgeneralized the US system (Katzenstein 1977, 598-99). The alternative approach proposed by Katzenstein was to show there are substantial differences in political and economic structures even among advanced industrial states and illustrate how these differences can influence each political economy's role in the world (Ibid, 590).

This pluralistic thread of *domestic sources* inquiry remains under-investigated and is only now getting more attention from historical institutionalists in IPE whose focus is primarily regulatory practices and the international competition to set regulation. This is intuitive because international regulation is often the product of domestic regulation and standards-exportation (e.g. accounting standards) (Posner 2010; Mosely 2010). This is certainly the case for intellectual property norms, standards, and decision-making procedures. The US-favored standards form the basis for the international regime. However, the *extent* of its success in exporting standards requires further examination.

Reversing the causal arrow, in the last decade the focus on international institutions and regimes has largely moved on from evaluating *emergence* to increasingly look at the interactions with and impacts on domestic politics (Checkel 2014, 74; Clapp and Helleiner 2012). Gourevitch provided an earlier articulation of this general approach in his 'second image reversed,' which examined the international sources of domestic politics (Gourevitch 1978). The most recent work on the impact of international rules on domestic regulatory authority has examined the narrowing of national policy options or "policy space" and the possibility for ongoing industrial policy autonomy through sectoral "carve-outs" (Natsuda and Thobum 2014, 1346). Also, in some cases the international regime bureaucracy has been examined as a source or modifier of norms

and rules (Chorev 2014, 631). This has challenged the assumption of the IO as “acquiescent receivers and passive vectors” of US policy (Ibid).

IP issues are fundamentally mediated at the domestic level and local IP laws only approximate the international regime. It is therefore difficult to imagine a study completely along structural lines without close attention to domestic factors as a source of international policy or as a substantial modifier of how the regime operates in practical terms. Rational choice and two-level game theoretic approaches may provide appropriate lenses for specific negotiation outcomes and tools to monitor political actor behavior. However, those approaches seem largely insensitive to institutions and history or take them as given. Institutions greatly inform actors’ calculation of interest and are important components of how domestic laws and practices evolve in the real world beyond the negotiation table.

The strengths and challenges of neorealism, neoliberalism, constructivism, regime complexes and the relative dearth of attention to domestic sources all point to the need for an alternative approach. An expanded pluralist approach could draw on multiple theoretical perspectives as appropriate for the facts of a given case. These challenges and the nature of IP regulation all point to a pluralist historical institutionalism as a potential framework.

An Historical Institutional Approach

Historical institutionalism is just beginning to migrate from comparative politics and American studies to IR and IPE. Efforts to date have struggled to differentiate between historical and market power factors. For example, demonstrating policy feedback and institutional salience within the polity of a powerful regime-maker as Sell (2010) does in

the domestic context of the US cannot truly differentiate HI from a realist, power-based argument. It simply explains the mechanics of interest articulation. Sell's use of HI to explain the emergence of TRIPS—with strong qualifiers regarding the importance of power—hints at an underlying realism to her argument. Her argument does not, however, reflect a *systemic* approach regarding historical institutionalism and “when institutional path dependence will matter at the systemic level” (Drezner 2010, 799). Rather, HI is framed as a mid-level approach somewhere “between the determinism of structural accounts and the voluntarism of rational choice approaches” (Sell 2010, 786). In trade and IP this is a particularly important perspective given that neither narrowly structural, nor narrowly voluntarist approaches have a very interesting story to tell. Of course powerful nations will often get their way when dealing with smaller rational actors. Furthermore, it is not particularly surprising that within those powerful states domestic interests will shape state preferences, and that once established, supporting institutions will help to reinforce those interests in various ways.³⁸

Trade and IP agreements are largely about negotiating *exceptions* to free trade, thus it is arguably the *details* and the process of practically *enacting* them that is truly interesting. These details can tell us more about the nuances of power than some largely self-apparent absolute measurement woven into a structural account. One value of HI is to show where other causal mechanisms can play a role in regulatory design and standard setting. For example, HI approaches have argued that technical capacity and its temporal sequencing can propel one regulatory standard to international prominence over others (Bach and Newman 2010).

³⁸ For example, acting as a focal point for coalition building.

Critics of the first forays into IPE by historical institutionalism identified the possibility for “repellence” – building up technical and institutional capabilities in order to develop a viable alternative to the hegemonic rules³⁹—as a response to the international regime (Drezner 2010, 796). This has been used as a basis to criticize the significance of sequencing. In essence, the argument is that because *repellence* to the international standard is possible, as opposed to solely reinforcing responses, the distribution of technical capacity—which is historically and institutionally contingent—is *less* significant (Ibid). In a world with multiple feedback possibilities including repellence, the significance of a regulatory first mover advantage (the sequence of capacity) is diminished and other factors such as market power will presumably be more determinative of regulatory outcomes.

Contrary to Drezner’s perspective on the implications of repellence, *repellence itself* can be a clear indication of capacity and can demonstrate the significance of institutional history. If meaningful repellence can be demonstrated as a counterpoint to tremendous market power asymmetry, then there may exist an argument for the conditions under which HI and technical capacity matter independent of power considerations: namely, in shaping domestic outcomes during and after the implementation of agreement standards. In this case, HI’s multiple varieties of feedback would not be damaging to the theoretical approach. This line of argument is thus distinct from the existing HI literature that has focused on the role of technical capacity in the competition to *set* an international regime standard. One contribution of this dissertation is to ‘save’ HI from one of its criticisms by re-conceptualizing the dependent variable according to its local characteristics (domestic implementation).

³⁹ See full definition Chapter 1.

Historical institutionalism is not a systemic theory and struggles with a lack of predictive capacity regarding policy feedback. Adherents of HI acknowledge this (Farrell and Newman 2010, 619). As such, HI is often grafted on to more established theories such realism, neoliberalism or constructivism (Ibid). However, HI itself emerged from a criticism of dominant theories to account for history, such as the dearth of attention to long-term causes and long-term effects. Since Paul Pierson's 2004 *Politics in Time* scholars, particularly in comparative politics, have paid more attention to these important issues of history and temporality. HI has not emerged as a robust rival to established *IR* theories, but rather more of a complementary or problematizing framework to those theories. Farrell and Newman argue "historical institutionalism fills a major gap in international relations theory: it sets out mechanisms that explain how actors respond to a changing environment" (Farrell and Newman 2010, 611). This is one of the features that make HI an excellent lens for trade and IP issues. Regulations, follow-on trade negotiations, and IP case law are constantly in a state of flux. Accounting for change is an important task and has led to some interesting insights on international regime formation from an inside-out perspective, as well as starting to address the "monoculture" in US IPE scholarship that had largely omitted HI accounts (McNamara 2009, 75-6; Fioretos 2011).

Historical institutionalists utilize mixed-method approaches and sometimes use process tracing to uncover *causal mechanisms* or "the intervening processes through which causes exert their effects" (Goertz and Mahoney 2010, 24; see also George and Bennett 2005, 205; Bennett and Checkel 2015). Mechanisms help to explain important questions such as: "How do national rule systems shape outcomes in global markets?"

(Farrell and Newman 2010, 609). According to the limited IPE literature to date, the answer typically involves powerful actors embedding themselves in the state's institutional structure, aligning state power to their interests: "interest groups and state preferences have typically co-constituted each other over time, so that states have helped create interest groups, which in turn come to shape state policy in specific directions" (Ibid, 620). Strict adherence to this *inside-out* approach (or the *outside-in* approach it counters) in explaining a regulatory regime's establishment potentially misses important causal mechanisms and policy feedbacks. If HI, as applied to IR, is to be true to its foundations in comparative politics it must temporally extend the causal chain.

Canada's case invites an "*inside-outside-in*" approach as a practical first step to extending the causal chain. For example, international standards are set and influenced by domestic institutions and actors such as the USTR; those standards then have an exogenous impact on the evolution of domestic institutions of both the standard-maker and the standard-taker. When new standards are adopted, an implementation-clash occurs where domestic institutions demonstrate resilience, actors opportunistically embed policy mitigations and regulatory outcomes only imperfectly approximate the original international standards. The standards that matter are thus not only TRIPS, but also the locally implemented and historically contingent regulations they produce.

This primary outcome variable is, however, not the end of the causal chain. Alternatively, an "*outside-inside-out*" approach would, following Sell (2010), take the initial sources of the international regime as given and look to how the international regime impacts domestic institutions: how the feedbacks of the ensuing implementation-clash impact the evolution of the regime going forward. For example, the experience of

implementation feeds back to inform the next iteration of the international regime as new agreements build on and layer over past treaties.

Historical institutionalism has been much more thoroughly explored in comparative politics than it has in IPE. Comparative political scientists have identified some common modes of institutional change including institutional layering. These are partially derived from the study of US Congressional institutions. Actors layer new measures on top of old to suit their interests thus making institutional development considerably disjointed (Schickler 2001, 25; Thelen 2003, 225-6). Institutions also change by means of “conversion” when they are repurposed to suit new objectives (Thelen 2003, 228). Sell (2010) adopts conversion as a conceptual framework for the empirical argument regarding a repurposing of trade agreements to IP promotion. This is a fruitful application of HI, but is incomplete in not explaining dynamics on the other side of the relationship. For example, if HI is significant there should be feedback and sequencing dynamics in the opposite direction as well. And if feedback and sequencing matter in this direction for the regime-taker then HI can be argued to be important, even in the context of tremendous power asymmetry. In some cases, institutional developments may even *offset* power asymmetry. Some HI scholarship has begun to document a similar dynamic (Posner 2010; 2009).

The literature is just beginning to take up the task of considering alternative causal mechanisms, but remains largely focused on the mechanisms of diffusion. For example, some work has used a constructivist lens to identify “socialization” as a causal mechanism and show various socialization pathways through government, elites and non-state actors (Morin et al. 2011, 95). While the identification of socialization is important

because it considers *some* standard-taker dynamics, it is still arguably an outside-in explanation of diffusion: the hegemon standard-maker is able to socialize the weaker party to its standards to the point that they exceed TRIPS requirements (Morin et al. 2011, 99).⁴⁰ As with much of the IPE scholarship on IP, this work has focused almost exclusively on those developing countries that IP critics are most interested in. There is an entire universe of underexplored causal mechanisms in the study of IP and few have been tied back to the broader debates on international regulation and institutional change.

Earlier institutional work in the rational choice tradition focused on the role of institutions in coordinating transaction costs. According to this work, institutional change is often incremental and relates to policy actor preferences and underlying changes in relative prices within a political economy (North 1990, 83). While there has been some co-merging of historical and rational institutional approaches, a defining difference remains the relative analytical privileging of ‘equilibrium order’ versus ‘historical process’ (Thelen 1999, 370, 381). Each will naturally produce different images of institutional change. Thelen’s way forward argues that the ‘key to understanding institutional evolution and change lies in specifying more precisely the reproduction and feedback mechanisms on which particular institutions rest’ (Thelen 1999, 400). This is

⁴⁰ This somewhat awkward quantitative examination of a social process uses such problematic variables for intellectual property norm socialization as the aggregate percentage of country’s population studying in the US, without making an explicit link to IP. It should be treated with caution. Beyond potentially problematic variables, aggregate foreign direct investment (FDI) stock and aggregate “US study” seemed to have much higher significance than participation in actual US IP “capacity building” events. When controlling for USTR “naming and shaming” the significance of each dropped considerably (Morin et al. 2011, 100). While providing an excellent review of the literature and a good *idea* for expanding the range of causal mechanisms to include socialization, the authors might have instead leveraged qualitative process tracing to explore such a social-centric causal mechanism. Also, failure to publish individual country scores for each of their variables made replication and country-specific critique problematic. This is, however, an appealing hypothesis for further examination.

the approached pursued herein, however, more policy feedback is observed than socialization.

To date, Thelen's way forward has only been accepted by a very few IR and IPE scholars, and there has been the beginnings of a debate on how HI might productively emerge in IR. Some argue for more attention to the "processes that shape, reproduce and alter international political institutions over time" (Fioretos 2011, 370). Others have aptly criticized a narrow focus on preference formation and institutional choice (Nexon 2012). Nexon advocates pluralism and that political analysts engage the full range of HI approaches.

The leading edge of HI in IR has been in the area of international regulatory development including the works cited above in the 2010 special issue of *Review of International Politics* as well as other work examining the privatization of international standard setting. The latter has sensibly argued against any separation of politics and domestic standards from international technocratic rule making (Buthe and Mattli 2011, 12). History shapes the ability to coherently articulate interests, which has a significant impact on who sets the international standard.⁴¹ Again, this work seems to focus on standard *setting* and privileges the relative sequence of domestic standard development in the articulation of interests. This is a compelling temporal extension of the independent variable; however, the dependent variable is still treated in relatively narrow temporal terms. This could be appropriate in the case of accounting standards, but is questionable for trade and IP where the extent of exceptions to free trade and the subsequent changes

⁴¹ "Technical expertise and financial resources are necessary but not sufficient conditions for successful involvement in global private-sector standardization. It is timely information and effective representation of domestic interest that confer the critical advantage in these regulatory processes, determining who wins or loses...[The] ability to speak with a single voice and effectively promote domestic preferences, however, varies—mostly for historical reasons" (Buthe and Mattli 2011, 12-13).

to domestic law are the real “outcomes” produced by the regime. A temporal extension of the *dependent* variable would also seem to be required to capture the most relevant effects of the international regime.

Regimes should be considered more in terms of *evolution*: as part of a multi-level policy feedback process. For example, a regime is not simply comprised of a single signed international agreement but involves multiple steps. These may include: 1) norm formation and diffusion; 2) international standard setting and specific rule-making; 3) practical domestic implementation by signatories; 4) integration dynamics between the new rules and local institutions; 5) follow-on agreements cited or linked to the original agreement such as bilateral and regional agreements; and even 6) pre-regimes, that “prime the pump”⁴² for the emergence of an international standard. For example, Canada played a key role in the emergence and inclusion of IP and investor state dispute settlement (ISDS) provisions within trade deals. By recognizing longer chains of a regime’s existence, it may be possible to distinguish institutional path dependence from market power factors in some cases. “Outcomes” cannot merely be defined as regime accession in exchange for some reciprocal benefit such as market access or investment inflow. The practical implications and details of regime implementation must also be considered as an integral *part* of that outcome. Thus the primary outcome variable considered herein is the practical extent of market exclusivity produced by the intellectual

⁴² The pump-primer metaphor reflects an intentional action that provides a source of legitimacy or impetus for some related action. It is often used in the context of fiscal policy following its use by Keynes. The term pump-primer is used here to describe a role that Canada has often played in international trade negotiations. For example, the Canada-US Free Trade Agreement played a key role as a normative precursor to NAFTA. Similarly, NAFTA played this role and helped to provide an impetus to finalize the multilateral Doha Round of trade negotiations. Canada’s negotiations with Europe in CETA helped to establish a template on many issues for a potential future US-EU Transatlantic Trade and Investment Partnership (TTIP). The idea here is that smaller negotiations can set a standard and facilitate a path for larger agreements.

property regime, not solely its negotiation or existence. The study changes the metric used for understanding IP policy in order to preserve space, in theory, for the reality that domestic institutions create cross-national variation of outcomes.

The present analysis offers another perspective on historical institutionalism's early forays into IPE. As suggested, a key task of this effort is to identify when policy feedbacks and path dependence can be, in a sense, separated from related power considerations. HI studies to date have demonstrated that technical capacity is one potential counter-balance to market power, and that sequencing of capacity development can impact regulatory outcomes. In the case of regime proliferation, where complexity is increasingly framed as an independent variable explaining various domestic and international outcomes, the same questions about determinacy independent of power and institutional history are relevant. In contrast to the bulk of the literature on trade and IP regimes, the analysis herein does not end with an international agreement and traces implementation to capture historically relevant policy feedbacks.⁴³

In summary, this dissertation advances the argument that intellectual property standards and the practical extent of market exclusivity are meaningfully shaped by the process of agreement implementation. Even under considerable power asymmetry, path

⁴³ This perspective also provides a distinct and original alternative to negotiations literature that typically look at one trade deal in isolation and focus on actor capabilities, negotiating objectives, and tactics. For example, some of the NAFTA negotiations literature posits that the right combination of "structure," the material resources that "bring actors to the table," and "process," the tactics that states employ, is the best way to divine negotiation outcomes (Robert 2000, 244). The negotiations literature tends to reflect empirically rich, agent-centric accounts written by negotiators, or largely based on negotiator interviews (Cameron and Tomlin 2000; Robert 2000; Hart, Dymond and Robertson 1994). Sometimes these accounts keep score of wins and losses based strictly on the negotiation context (Robert 2000). They explain "how countries negotiate" with comprehensive "blow-by-blow" accounts on a range of issues areas within an agreement (Cameron and Tomlin 2000). They do not seem to put those win-sets in a broader societal or historical context, nor consider how the practical details of implementing trade commitments might alter the conception of 'winning.' This approach may be sufficient for relatively static outcomes such as a negotiated tariff rate. However, it seems less suited to agreements on complex regulatory processes relevant to the knowledge economy such as the "new issues" of investment and intellectual property protection. In these areas, the details of domestic implementation are critical.

dependence matters where national institutions and politics have capacity to shape outcomes: via the technocratic interpretation and domestic implementation of the international standard. Market power dynamics between standard-maker and standard-taker nations are undeniably a central factor in the establishment of the international regime; however, institutions shape its details. This builds on the emergent HI literature in IPE that has stressed sequencing of technical capacity or the institutional sources of political coalition formation (Bach and Newman 2010; Sell 2010).

In keeping with Bennett and Checkel (2015), a wide empirical net is cast to capture related phenomenon such as price regulation for patented technologies, case law, and domestic procurement institutions that might not be routinely considered in a technical accounting of the IP regime.⁴⁴ This diversity produces some interesting insights related to the range of policy feedbacks at play as international and domestic IP regimes integrate and evolve over time. Each chapter examines different policy feedbacks and contributes to explaining the intersection of international standards and local institutions.

⁴⁴ Also in keeping with Bennett and Checkel (2015), the broader discursive context is examined for contributing factors and sources are considered critically for evidentiary bias. The temporal and idiographic or “level-of-detail” parameters are identified and justified. Alternative theoretical explanations are robustly assessed.

Chapter 3 - Regulatory Feedbacks: Mitigating Regulatory Institutions

This chapter examines the regulatory aspects of Canada's negotiation and implementation of the Canada-United States Free Trade Agreement (the FTA), the North American Free Trade Agreement (NAFTA), and Canada's compliance with Trade Related Aspects of Intellectual Property Protection (TRIPS) standard. The chapter shows that Canada had considerable regulatory autonomy and an ability to constrain the practical extent of increased patent protection through regulatory pricing controls.⁴⁵ Through the trade treaty implementation process, Canada's domestic institutions narrowed the *effective* scope of market exclusivity provided under the international standards. Despite considerable market power asymmetry with the US, Canada preserved room for its domestic institutions by helping to shape the specific language of the international standard.

Market power theory would predict that small market powers are not likely to be effective in mitigating trade commitments that are contrary to the interests of larger market powers. We would expect global standards advanced by the hegemon to essentially alter or replace domestic rules without a strong compensatory domestic institutional response. Furthermore, small powers should only secure minor concessions and not be able to sway important elements of regime design nor protect unlimited future regulatory capacity. Evidence contrary to either expectation (i.e. a strong institutional response, full protection of regulatory capacity, path dependent implementation

⁴⁵ Regulatory pricing controls were comprised of: a system linking the price of patented products to an international basket of prices for that same product such that Canadian prices would not exceed various international benchmarks; controls over price fluctuations (increases) to provide price stability and protect consumers from significant price increases; and a system of monitoring the R&D investments by patentees.

outcomes) would be a smoking gun that other important factors beyond market power help to explain international regulatory design and implementation.

The analysis starts process tracing in Canada's pre-1987, pre-FTA era. In 1984, the influential *Eastman Commission*⁴⁶ was struck to analyze and provide recommendations on Canada's patent protection regime for pharmaceuticals that featured a strong role for compulsory licensing.⁴⁷ This period is chosen to start process tracing because it marked 1) the establishment of the Patented Medicine Prices Review Board, a powerful price regulation institution that would come to play a role in later trade-related policy changes under TRIPS/NAFTA; and, 2) the consolidation of Canada's anti-intellectual property (IP) interest coalition. Starting any later, such as during the trade agreement negotiation phase, would omit important historical causes and context related to NAFTA/TRIPS implementation. These types of domestic historical and institutional factors are underrepresented in dominant realist or "market power" based explanations in IPE.⁴⁸ For example, bargaining theory accounts (see Wagner 1988) correctly identify asymmetrical interdependence as a source of power, but overemphasize this to the detriment of other potential sources of power such as entrenched institutions.

Following analysis of the pre-NAFTA context, the chapter considers the significant impact of these Canadian institutions on the TRIPS and NAFTA negotiations and implementation. The distinction between negotiation and regulatory implementation is important, as many key details are not specified in a negotiated text. Despite its

⁴⁶ The Commission was a key precursor to the 1987-88 and 1993-94 *Patent Act* Amendments that implemented IP-related outcomes of international trade negotiations.

⁴⁷ Compulsory licences set the tariff rate when the state compels a patent owner to license its technology to some other producer in service of a public policy objective. This came to be most associated with the pharmaceutical sector, as brand drug manufacturers were often compelled to license their technologies to generic producers in the pre-TRIPS era.

⁴⁸ Newman and Posner (2010) provide a good critical overview and identify several examples of a "dominant" market power approach including Drezner (2007); James and Lake (1989); and Wagner (1988).

importance, implementation is not typically central to negotiations analysis (for examples of excellent negotiations work see Hart, Dymond and Robertson 1994; Cameron and Tomlin 2000; Robert 2000). From a theoretical perspective, this empirical work shows that local political institutions and historical policy choices can powerfully shape the implementation of international regulatory standards. Regulatory history is an important determinant of negotiating positions, negotiating outcomes, and how those outcomes are implemented in domestic law and regulation. In short, trade-related regulatory regimes are historically cumulative and institutionally contingent.

The Pre-FTA Context: Lacking IP Institutions, Canada's Compulsory Licensing Regime Consolidates a Powerful Stakeholder Coalition

This section explores Canada's pre-US trade agreement era. It argues that Canadian IP policy is significantly shaped by a history of compulsory licensing. This system was based on similar policies of Canada's colonial parent Great Britain (Eastman 1994, 278). Canada instituted a British-style system of compulsory licensing on active pharmaceutical ingredients in 1923 (Eastman 1985, xxxiv). In 1969, Canada significantly expanded this regime to lower the prices of pharmaceuticals through compulsory *import* licensing for finished products (Ibid). While Britain abandoned compulsory licensing in 1977, Canada's compulsory licensing regime prevailed until it was significantly modified in 1987. It was then effectively abolished in 1993 as part of Canada's NAFTA and TRIPS commitments. In advance of these reforms, compulsory licensing helped to solidify a powerful interest coalition that would shape Canada's future approach to intellectual property rights.

In the lead up to negotiation on the Canada-US Free Trade Agreement (the FTA), the issue of intellectual property had been a “top bilateral irritant” with US multinationals concerned about delays to patent reform following the guidance set out in the 1985 *Eastman Commission of Inquiry on the Pharmaceutical Industry*⁴⁹ (Hart, Dymond and Robertson 1994, 400). The Eastman Report recommended changes to Canada’s patent regime which had prevailed since 1969⁵⁰ and was a major factor in the development of a strong generic pharmaceutical sector in that it provided for compulsory import licences and required only a limited licensing royalty of 4% of the licensee’s selling price (Eastman 1985, xix). Strong revenue growth with only limited licensing fees was a major source of power for the burgeoning Canadian generic industry.

This era was marked by much lower drug expenditures than experienced today. In 1990 there were only \$3.8 billion in total *prescription* pharmaceutical sales in Canada and of this only \$1.7 billion or 45% were *patented* drugs. Generics had reached around \$300 million in sales representing 8% of the total industry and the remainder was comprised of non-patented brand name drugs with \$1.8 billion in sales or 47% of the industry (PMPRB 2004, 9). Following patent reforms, Canada would not return to this high level of spending on non-patented brand drugs, which by 2003 had fallen to 21% of a total \$15 billion market (Ibid).⁵¹ Even under patent reforms discussed herein, by 2013

⁴⁹ Harry Eastman, Commissioner (1985) “Commission of Inquiry on the Pharmaceutical Industry” (Eastman Report) Published February 28, 1985, accessed June 20, 2015, <http://epe.lac-bac.gc.ca/100/200/301/pco-bcp/commissions-ef/eastman1985-eng/eastman1985-eng.htm>

⁵⁰ In 1965-1968 the “Harley Commission,” whose terms of reference from Cabinet included “...to consider and recommend, as it may deem expedient...a comprehensive and effective program to reduce the price of drugs,” conducted public hearings on how to do so. In 1969 Parliament passed Bill C-102 to facilitate compulsory import licensing in a direct and successful effort to reduce drug costs (Lang 2003, 4-5).

⁵¹ By 2003, generic sales had vaulted to \$1.7 billion comprising 11.3% of the now \$15 billion industry and brand sales dominated the market with \$10.1 billion or 67% (PMPRB 2004, 9).

generic companies constituted three of the top ten pharmaceutical firms in the country.⁵² The extant policy literature on the compulsory licensing era in Canada attributes the rise of the generic industry to this incentive structure (Cohen 2004, 7). The policy was also heralded in generic industry advocacy materials. According to one major generic industry stakeholder, “as a result of [compulsory licensing] legislation there was an unprecedented boon to the generic companies to expand rapidly and make available good quality generic pharmaceutical products to the public at affordable prices” (Dan 1997).

Unsurprisingly, the US branded pharmaceutical industry was highly critical of Canada’s compulsory licensing regime and leveraged its proximity to the United States Trade Representative (USTR) and the FTA negotiation to advocate for reform in Canada.⁵³ The US industry also presented the Canadian government with polling data suggesting that Canadians were strongly in favour of patent reforms.⁵⁴ Despite the push from the US private sector and somewhat contentious politics in Canada, intellectual property protection was new to bilateral trade negotiations. It was seen as somewhat of a peripheral issue that US negotiators used periodically to bludgeon Canada for what it

⁵² Government of Canada, Industry Canada (2014) “Canadian Pharmaceutical Industry Profile” accessed December 23, 2015, https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html Apotex is the 3rd with \$1.19 billion in annual sales, Teva is 6th with \$0.97 billion, and Pharmascience is 9th with \$0.77 billion.

⁵³ For example, the industry leveraged its position within the primary private sector US advocacy group to the USTR in the FTA negotiation, the “Advisory Committee on Trade Negotiations,” which was chaired by Ed Pratt, Chief Executive Officer of Pfizer (Hart, Dymond and Robertson 1994, 400).

⁵⁴ Pharmaceutical Manufacturers Association of Canada Letter March 30, 1987, to Patricia Carney Minister for International Trade: “more than eight in ten Canadians (82%) are in favour of the Federal Government putting into place a law to protect pharmaceutical discoveries with patents – as long as there is a way of making sure drug price increases would not be higher than the rate of inflation. Bill C-22 includes such a provision. Also almost two out of three Canadians (65%) after hearing the main arguments for and against Bill C-22 regarding patent protection for new medical discoveries believe that the legislation is a good thing.” Accessed from Library and Archives Canada.

viewed as unsatisfactory draft patent reform legislation (Hart, Dymond and Robertson 1994, 179, 225).⁵⁵

Canada's compulsory licensing regime was a central topic of bilateral discussion. The impacts of the policy had been reviewed extensively by Canada in the mid-1980s and were documented in a series of reports. In 1983, what was then Consumer and Corporate Affairs Canada, Bureau of Policy Coordination conducted a "Survey of generic drug manufacturers," coauthored by its Director Tom Brogan (Brogan and Trepanier 1983).⁵⁶ The report assessed the size and growth of the generic industry that had exploded under this policy framework and had booked an impressive average annual growth rate of 20% from 1980-1982. Compulsory licence revenue comprised around 30% of the generic drug sector. This ranged by company with some reporting as much as 42% of their sales resulting from this policy tool that Canada and other Commonwealth countries had borrowed from Britain (Ibid, 3,4). While still a relatively small business sector (approximately 1000 employees), full-time employment in the generic drug industry was growing on average 4.5% per year in 1980-1983, a rare point of employment strength in a period of acute recession and historic 12% unemployment in Canada.⁵⁷ The report also showed that firms were increasingly using Canada as a base for exports and decreasing

⁵⁵ As noted by FTA negotiators Hart et al., from the outset of negotiations in April-June 1986 "intellectual property, which neither side appeared to understand, was consigned to a working group with instructions that the chief negotiators should not be detained further on it until a text was ready" (Ibid, 164). Despite considerable discussion, this IP chapter never materialized in the final agreement because the US "was not prepared to compromise on its demand that Canada dismantle compulsory licensing of pharmaceuticals" (Hart, Dymond and Robertson 1994, 382).

⁵⁶ The report was part of a policy review of the compulsory licensing provision under section 41 of the *Patent Act* and appears to be one of the first government analyses of pre-FTA compulsory licensing. This report is available through Libraries and Archives Canada.

⁵⁷ Government of Canada, Employment and Social Development Canada (2012) "Employment Insurance Monitoring and Assessment Report," accessed August 1, 2015. <http://www.esdc.gc.ca/eng/jobs/ei/reports/mar2012/chapter1.shtml>

Canada's reliance on drug imports, with 168% export growth between 1979 and 1982 (Ibid, 7, 8, 10).⁵⁸

Compulsory licensing was helping to fulfill industrial and social policy objectives while at the same time creating a new and increasingly powerful domestic constituency. The Brogan report was not prescriptive, but reflected an early attempt by the government to quantify the industrial impacts of its intellectual property policy.⁵⁹ This was also an attempt to create a more accurate picture of the domestic industry most impacted by any future changes to the compulsory licensing regime. Canada's domestic regime was attracting the attention and ire of the US pharmaceutical industry and was a likely target for reform.

The Eastman Commission 1985

In April 1984,⁶⁰ Dr. Harry Eastman was given a mandate by Order in Council to report on the "current situation" in the pharmaceutical industry in Canada and make recommendations on proposals for patent protection and other incentives. Eastman noted that the origin of his Commission's mandate was concern over Canada's compulsory

⁵⁸ In 1981, imports represented 30% of medicine sales while the generic industry only derived 19.7% of its sales from imports. The reverse engineering required to replicate US and European health technologies also resulted in steady 24% average growth in Canadian generic industry research and development (R&D) investment (Brogan and Trepanier 1983, 9). R&D was a major promotional objective of government that also benefited Canada's university sector.

⁵⁹ The report's author, Tom Brogan, led the intellectual property policy division responsible for amendments to compulsory licensing reforms under Bill C-22 and held the pen on much of those legislative changes. Brogan was a key architect of the Patented Medicine Prices Review Board (PMPRB) and later served as its interim Director from December 1987 to June 1989. Brogan served under inaugural PMPRB Chair Professor Harry Eastman whose 1985 report laid the groundwork for the establishment of the quasi-judicial tribunal. The PMPRB was established under Bill C-22, and as discussed below, came to become a key policy mitigation associated with trade-related patent protection. The growth of the generic industry under compulsory licences complicated Canada's interests in the trade negotiation. Canada wanted to promote brand sector research and development and facilitate trade with the US but it now had to balance these objectives with the interests of the growing and powerful generic export sector.

⁶⁰ Twelve months after the May 1983 publication of Brogan's generic drug industry study.

licensing policy (Eastman 1994, 279). The Eastman report was a detailed 474-page study that spanned regulatory measures and many other important facets of the pharmaceutical industry.⁶¹ The Commission heard from members of the Canadian medical establishment as well as members from both sides of industry including key generic industry stakeholders Barry Sherman,⁶² founder of Apotex, and Leslie Dan,⁶³ founder of Novopharm.

The Eastman Report was supportive of compulsory licences but called for raising the relatively low 4% tariff paid by generic producers to branded drug manufacturers forced to license their products (Eastman 1985, xix). Specifically, Eastman recommended a complex framework that would collect royalties from licensees and put them into a common *Pharmaceutical Royalty Fund* to be redistributed to brand owners based on licensee sales and the licensor's Canadian research and development-to-sales ratio (R&D-to-sales) (Eastman 1985, xxi-xxii). This proposed functional link between generic company revenue, brand company revenue and a brand's R&D contributions was never implemented because the brand sector made a non-binding commitment to invest 10% of sales into R&D as part of patent reform legislation, Bill C-22 (1987). The government also pointed to \$770 million in actual announced industry investments in support of Bill C-22's passage.⁶⁴ The lack of a hard and binding Eastman-style R&D

⁶¹ The most central material and recommendations related to patent and licensing policy and took the various reports by the Bureau of Consumer Affairs under the direction of Tom Brogan one step further with additional analysis and specific recommendations.

⁶² Net worth \$4.6 billion, 13th most affluent person/family in Canada in 2015. Canadian Business. "25 Richest Canadians, 2016" accessed December 4, 2015 <http://www.canadianbusiness.com/lists-and-rankings/richest-people/top-25-richest-canadians-2016/image/26/>

⁶³ Net worth \$1.06 billion, and 83rd most affluent person/family in Canada in 2015. Canadian Business. "100 Richest Canadians, 2016" accessed December 4, 2015 <http://www.canadianbusiness.com/lists-and-rankings/richest-people/top-100-richest-canadians-2015/>

⁶⁴ Minister Harvie Andre, Statements to House Committee study on Bill C-22, Tuesday, December 16, 1986 (1555). The 10% R&D to sales ratio commitment was met from 1993-2000 for the members of

formula was also likely attributable to its functional complexity which made industry's non-binding commitment attractive to government. Lack of binding R&D measures was also a major point of contention between the Progressive Conservative government and Liberals in the Senate.⁶⁵

The Eastman report contains a succinct illustration of the interest coalition of generic producers and provincial government payers that was institutionalized under the compulsory licensing regime:

Compulsory licensing to import gave rise to the possibility of increased competition. At the same time, provincial reimbursement plans increased sensitivity to price differentials at the pharmacy level and exploited the opportunities for lower prices through generic substitution made possible by the federal legislation. Both together permitted the growth of large and profitable Canadian-owned generic pharmaceutical firms, which in turn has led to lowered prices to consumers and taxpayers (Eastman 1985, xxxvi).

In other words, prominent observers at the time clearly linked the compulsory licensing policy to the formation of a powerful interest coalition. The outcome of lower prices also had tremendous popular support. Provincial governments which enjoyed regulatory power over professions, made use of the federal IP framework to encourage pharmacists

the main brand pharmaceutical industry association, Rx&D (PMPRB Annual Report 2003, accessed December 4, 2015, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=908>). This has gradually declined back to 1988 levels as the multinationals' business model in Canada increasingly moved towards acquisitions and the provision of venture capital and less into direct Canadian R&D spending under the non-binding target. Industry frequently argues the PMPRB's R&D calculation methodology is out of date in that it does not capture R&D spending from global clinical trial budgets controlled by a company's international head office (as opposed to the Canadian subsidiary) and other investments that benefit Canada such as the provision of venture capital funds. Industry Canada internal documents suggest that the government is aware of this changing landscape and the pressures on industry: "The pharmaceutical business model is changing... The return on R&D investment is declining, necessitating consolidation and a new R&D model... To combat lower R&D returns [multinational enterprise (MNE)] brand companies are investing in home-grown Canadian biopharmaceutical [small and medium sized enterprises (SMEs)]... many new drugs coming to market are complex products or biologics, with longer development times and more stringent clinical trials... Generics invest in R&D, but [are] not aimed at developing new, innovative drugs." "Pharmaceutical Proposals in the Canada-European Trade Negotiations: Presentation to the Minister of Industry" Draft – Secret - February 9, 2012.

⁶⁵ "Honourable senators, there are no commitments in Bill C-22 as passed by the House of Commons dealing with R&D—not one commitment." Senator Ian Sinclair, Senate Debates, October 28, 1987 (2093).

to engage in generic substitution of branded drugs for licensed generic drugs. For many years, pharmacies also received substantial rebates from generic companies to promote generic products. This practice became so central to the pharmacy business model that many provincial governments outlawed the practice beginning with Ontario in 2006 under Bill-102.⁶⁶ Sparked initially by the compulsory licensing policy, these factors helped to entrench and institutionalize a stakeholder coalition that would come to have major influence on future intellectual property policy as it advocated its interests by leveraging the interests of consumers of patented technologies.

Canada's policy was a close replication of 1923 British compulsory licensing legislation that Britain had repealed in 1977. Despite British reforms, Canada's policy remained law until Bill C-22 in 1987. This ten-year lag was critical to the generic industry's development in Canada. For example, Eastman reported that there were 559 licence applications to import and sell between the 1969 *Patent Act* amendments that permitted *import* licences and January 31, 1985. This compared to only 49 applications from 1935 to 1969 for patented *processes*, 22 of which were abandoned or withdrawn (Eastman 1985, 2). Up until 1969, compulsory licences were only available for drug process patents, not finished imported goods.⁶⁷ According to Eastman, the *Patent Act*

⁶⁶ Statutes of Ontario (2006) "Transparent Drug System for Patients Act" Bill 102, Section 11.5 (1) "Rebates etc.," accessed December 3, 2015, http://www.ontla.on.ca/web/bills/bills_detail.do?locale=en&BillID=412&BillStagePrintId=773&btnSubmit=go; According to one account, rebates paid by generic manufacturers to pharmacies in Ontario were up to 60% of the dollar value of drugs sold, massively inflating the price of generic drugs (Silversides 2006). See also Sean Fine, "Supreme Court upholds Ontario ban on house-brand generic drugs" *Globe and Mail*, November 22, 2013, accessed August 27, 2015, <http://www.theglobeandmail.com/report-on-business/industry-news/the-law-page/supreme-court-upholds-ontario-ban-on-house-brand-generic-drugs/article15561005/>

⁶⁷ Up until Bill C-22 (1987), Canada only allowed *process* patents for pharmaceuticals. Bill C-22 introduced patents for natural occurring substances intended for food or medicine when linked to a process. This was essentially a transition measure. After a period of 4 years, the prohibition on patents for actual medicines would expire (per 41(1.1)) and it would become possible to patent them directly. Per 41(1), "In the case of inventions relating to naturally occurring substances prepared or produced by, or significantly

amendments in 1969 enabling compulsory *import* licences was the product of Canadian government studies in the 1960s showing that drug prices were higher in Canada than elsewhere internationally. Concern over drug costs was not unique to Canada, as countries such as France had maintained a full ban (until 1960) or partial ban (until 1978) on pharmaceutical patents (Ibid). However, Canada's history of concern over cost would be a recurring theme, a driver of policy, and source of leverage for the generic industry whose advocacy material on intellectual property protection routinely employed cost concerns and was closely aligned with the concerns of provincial government drug insurance plans (public payers).

Bill C-22, 1987: A New Price Regulation Institution is Born to Counter-Balance Trade-Related IP Commitments

This section examines Bill C-22 and introduces the Patented Medicines Prices Review Board (PMPRB).⁶⁸ The PMPRB was established as an important check and constraint to expanded IP protections that the US pushed Canada to introduce in 1987 in conjunction with the Canada-United States Free Trade Agreement (the FTA). Domestically, the PMPRB was a major part of how the government would sell limitations to compulsory licensing to the public.⁶⁹ The PMPRB would be strengthened throughout the years as Canada introduced new trade-related IP protections.

derived from, microbiological processes and intended for food or medicine, the specification shall not include claims for the resulting food or medicine itself, except when prepared or produced by or significantly derived from the methods or processes of manufacture particularly described and claimed" (Bill C-22 1987, 1184).

⁶⁸ A scanned version of Bill C-22, *An Act to amend the Patent, Act and to provide for certain matters in relation thereto, 1987*, is available through Library and Archives Canada's electronic Canada Gazette database.

⁶⁹ This was true both for Bill C-22 and later for Bill C-91 associated with NAFTA.

Despite considerable discussion, no intellectual property chapter was ultimately forthcoming in the FTA. Canadian and US lawyers concluded final text negotiations for the FTA on December 9, 1987 and the agreement was tabled in the Canadian House of Commons on December 12 (Hart, Dymond and Robertson 1994, 442).⁷⁰ In the context of the broader ongoing General Agreement on Tariffs and Trade (GATT) discussions, the US did not want to have its first IP chapter in a trade agreement be one with minimal protections. Canada's concessions on IP in the related Bill C-22 were sufficient for the US to abandon the proposed IP chapter and proceed with the agreement (Ibid, 306, 341, 383). The FTA was seen by the US as a potential pump-primer⁷¹ for the broader insertion of intellectual property protection into international trade agreements, but it was not until NAFTA in 1994 that this actually materialized. NAFTA was the first international trade agreement to include robust IP provisions (Hussain 2012, 83). However, the contentious FTA negotiations on IP clearly set the stage for this development and Bill C-22 was widely regarded as being linked to its agreement (Naylor et al. 2015, 90).⁷² The

⁷⁰ The Canada-United States Free Trade Agreement (the FTA) entered into force January 1, 1989.

⁷¹ See notes to page 57.

⁷² The Senate debate on Bill C-22 makes this point clear. Senator L. Norbert Theriault quotes the chief U.S negotiator on the FTA to highlight its role in the negotiations: "Ever since the production of the new draft of Bill C-22, the Mulroney government has been using it as a chip in the bargaining over a free trade agreement with the United States... a memorandum to Congressmen from the U.S. chief negotiator in the free trade talks, Peter Murphy, leaked to the Toronto Star, shows that Bill C-22 is, in fact, a very important part of the negotiations under way: 'Intellectual property is another priority item for the U.S. In these negotiations we are trying to convince Canada that it is in our mutual interest over the long run to strengthen IP – meaning, intellectual property – protection. We have put together a draft text, reviewed by our private sector and we will use this as a basis for the negotiations. We have also indicated that we are not satisfied with Canadian compulsory licensing of pharmaceuticals or the lack of copyright for cable re-transmissions and that these must be resolved to have an agreement.'" Senator L. Norbert Theriault, quoting Peter Murphy, Senate Debates, June 25, 1987, (1404). Senator Sidney L. Buckwold makes a related point when reflecting on committee testimony: "during the hearings of the committee brief after brief said point blank and it has never really been denied-that this bill is part of the free trade deal; that somewhere along the line the U.S., which is irked by the fact that Canada has not, in their opinion, protected intellectual property in a satisfactory way, is insisting that the level playing field has to be established in order that free trade between our two countries can be looked at seriously." Senator Sidney L. Buckwold, Senate Debates, Nov. 18, 1987 (1346).

government of the day downplayed this link, however, due to the contentious politics associated with intellectual property.

Bill C-22 was based on creating a balance of producer and consumer interests. It operationalized five key pillars: intellectual property protection, industrial benefits, multilateral relations, health care, and consumer protection.⁷³ The responsible Minister stated that the intent of Bill C-22 was to strike a balance between enhancing Canada's research and development investment climate and consumer protection:

In essence, the amendments I propose in Bill C-22 will create a climate favourable to new investment in research and development by giving patent holding pharmaceutical firms in Canada a guaranteed period of protection. These changes will also ensure consumer protection by creating a drug prices review board to monitor drug prices. The amendments will also allow the government to review and alter the policy after a period of four years, and again in the tenth year to ensure the policy works to the benefit of all Canadians...

The question of intellectual property, and respect for it, is on the General Agreement on Tariffs and Trade, the GATT. And it is entirely possible that in fact we might have been compelled by some future GATT agreement to make these changes, in order to remain a member of GATT. Doesn't it make a lot more sense that we do it ourselves?⁷⁴

The automatic review and ability to amend the legislation was an integral component from the beginning. Canada seemed to recognize the benefits of making changes on its own terms in advance of policy proposals being entrenched in the multilateral GATT. Another explicit intent was to lock in lower drug prices for Canada than existed in the US: "We are calling for the creation of a drug prices review board, to monitor the existing prices of drugs, and the prices of any new drugs to ensure that the kind of market

⁷³ Minister Harvie Andre, Statements to House Committee study on Bill C-22, Tuesday, December 16, 1986 (1530).

⁷⁴ Harvie Andre, Second Reading of Bill C-22, House of Commons Debates, November 20, 1986, 1369, accessed October 15, 2016, http://parl.canadiana.ca/view/oop.debates_HOC3302_01/1374?r=0&s=1; see also CPAC House of Commons Debates, coverage at 3:10:00 and 3:19:00: <http://www.cpac.ca/en/programs/house-of-commons/episodes/90004461/>.

situation that exists now, where our drug prices are at about 80 per cent of those of the United States, remains in place.”⁷⁵

Bill C-22⁷⁶ received royal assent on November 19, 1987, just days before the FTA was tabled in December of 1987 (Bill C-22 1987). It provided the Governor in Council with regulatory powers regarding the “form and contents of applications for patents” (Bill C-22 1987, 1176).⁷⁷ The bill articulated many basic requirements for a patent system regarding filing and priority dates,⁷⁸ definition of a “patentee,” provisions for “prior art”⁷⁹ regarding patent applications, provisions for a register of patents, applications fees, and so on. More substantively, Bill C-22 extended the length of all patents from 17 to 20 years but only for patents granted after the legislation came into force (Ibid, 1202). Importantly, it limited compulsory licences granted under section 41 of the *Patent Act*. A ten-year prohibition on compulsory licences to import would apply for medicines with a “notice of compliance” (NOC)⁸⁰ granted after June 27, 1986 (Ibid, 1185). The

⁷⁵ Harvie Andre, Second Reading of Bill C-22, House of Commons Debates, November 20, 1986, 1372, accessed October 15, 2016, http://parl.canadiana.ca/view/oop.debates_HOC3302_01/1374?r=0&s=1

⁷⁶ Harvie Andre, Minister of Consumer and Corporate Affairs tabled Bill C-22 in Parliament.

⁷⁷ It also carried into effect the terms of the *Patent Cooperation Treaty* signed in Washington, June 19, 1970.

⁷⁸ According to the World Intellectual Property Organization (WIPO), the priority date is the date of first filing in a Paris Convention signatory country. This allows a patentee to claim the date filed in one country as the same date in other countries, thus conferring priority over other applications filed after that date. This is an important tool for inventors, especially in competitive markets, given that IP rights are typically conferred to those “first-to-file” a patent. For more details see: WIPO, (2015) “What is Meant by Priority Date,” accessed October 20, 2015, http://www.wipo.int/sme/en/faq/pat_faqs_q9.html Canada moved to a first-to-file system under C-22.

⁷⁹ Prior art is defined in different ways, but is generally linked to an existing state of patented knowledge. The Patent Cooperation Treaty defines Prior art as: “Everything which has been made available to the public before the relevant date anywhere in the world by means of written disclosure and which can be of assistance in determining whether the claimed invention is new and involves an inventive step (i.e. is not obvious) for the purposes of international search and international preliminary examination.” WIPO, (2015) “Glossary,” accessed October 20, 2015, <http://www.wipo.int/pct/en/texts/glossary.html#P>

⁸⁰ A Notice of Compliance, or NOC, is the notification provided by Canada’s federal drug regulator, Health Canada, when a therapeutic product has been successfully reviewed for safety and effectiveness and has approval to be marketed in Canada. Like other national regulators such as the US Federal Drug Administration (FDA), Health Canada maintains a searchable database of all products approved for use within Canada.

prohibition included an attempt by Canada to phase in the protections for products with NOCs dated before June 27, 1986. This entailed a seven-year prohibition if an NOC had already been granted to a generic manufacturer but no licence had yet been issued; a seven-year prohibition if a licence had been issued to a generic manufacturer but not an NOC; or an eight-year prohibition for those products with no current licensee and no generic NOC (Ibid).⁸¹ In other words, existing licences were to stand as valid provided Health Canada had also issued marketing approval to the generic licensee. This was a commitment the government made to stakeholders that it would not remove existing licences under Bill C-22.⁸² The bill was hotly contested and was held up in the Senate in the summer and fall of 1987.⁸³

The United States was undoubtedly aware of these legislative manoeuvres and evidently viewed them as an acceptable compromise given that the parties ultimately proceeded with the FTA. However, it is also possible that the US saw this as an

⁸¹ Per section 41.11 subsection 4 “Restriction of certain licences,” those restrictions did “not apply in respect of any licence pertaining to a medicine where on June 27, 1986, a licence has been granted in respect of the medicine and a notice of compliance in respect of the medicine has been issued to the licensee” (Bill C-22 1987, 1186).

⁸² Michel Cote, Minister of Consumer and Corporate Affairs, Letter to Canadian Federation of University Women, June 16, 1986, accessed from Library and Archives Canada: “[the estimated \$211 million of annual savings as a result of compulsory licensing] will continue since at no time and under no circumstances has the Government considered removing or limiting the sale of those generic products now available.” Here Cote was responding to the Canadian Federation of University Women (CFUW) who advocated against C-22 in light of its concerns over potential drug cost increases, particularly for the elderly. CFUW and the Canadian Drug Manufacturers Association (generic industry) shared information on their advocacy “We will add [CFUW Legislation Committee] to our mailing list and sen[d] them relevant information, as it becomes available...I would like tocommend you on your letter to the Honourable Michel Cote, a very effective statement of our mutual concerns and interests.” Debra Eklove, Executive Director, Canadian Drug Manufacturers Association letter to CFUW, September 12, 1985, accessed from Library and Archives Canada.

⁸³ Harvie Andre, Minister of Consumer and Corporate Affairs, letter to “Colleagues,” including Patricia Carney, Minister for International Trade October 6, 1987. According to media reports attached to the Minister’s memo, Liberal Senators wanted a prohibition on compulsory licences of only 4 years, whereas C-22 provided for 10 years, and the generic industry wanted a compromise of 7 years. Montreal Gazette, “Few back Senate delay of drug bill, poll finds” October 2, 1987. The generic industry supported its argument with polling data that the government viewed as employing “loaded questions” and not undermining the bill being obstructed by the Senate: “despite these leading questions, the results of the poll overwhelmingly support the passage of Bill C-22.”

opportunity for future forum shopping.⁸⁴ In 1999 the US successfully challenged Canada at the World Trade Organization and received a favourable ruling in 2000 that found the distinction between pre- and post-1987 patents that Canada had advantageously incorporated into Bill C-22 indeed violated TRIPS (Lexchin 2003, 15; Douglas and Jutras 2008, 2-3, 7).⁸⁵ Canada eventually amended domestic law in June 2001 to modify this distinction to be TRIPS compliant through Bill S-17.⁸⁶ This bill also addressed another provision regarding stockpiling that was ruled inconsistent in a separate WTO challenge against Canada by the European Communities (Smith 2001).⁸⁷

Canada did not decide to abolish compulsory licensing in 1987, deciding instead to limit such licenses to 10 years while simultaneously extending all patents to 20 years. This was effectively a compromise that excluded the pharmaceutical industry from the

⁸⁴ The term “forum shopping” can be applied in various areas but is often discussed in a legal, policy and regulatory context. Generally, it refers to litigants or stakeholders searching for the most favorable venue to secure advantage. In a legal context this may be the most advantageous court system or international arbitration process to litigate, or to re-litigate when another fails to secure satisfactory outcomes. In policy terms forum shopping may be used to find the most advantageous jurisdiction or venue to advance an interest through legislation. De Bièvre and Thomann provide one application of this general concept to Global Intellectual Property Regulation (De Bièvre and Thomann 2010).

⁸⁵ See also: WTO, “Canada- Pharmaceutical Patents DS114,” accessed November 5, 2015, https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds114sum_e.pdf

⁸⁶ Statutes of Canada (2001) “*An Act to Amend the Patent Act*,” Bill S-17, accessed September 5, 2015, <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=2331026&File=16#1>.

⁸⁷ As illustrated by the Library of Parliament assessment of Bill S-17, not all patents would be impacted by the legislation: “Clause 1 would amend section 45 of the *Patent Act* by providing that for patents filed before 1 October 1989 where the 17-year term had not expired before the date on which the section came into force, the patent term would be the later of 17 years from the date the patent had been issued or 20 years from the date the patent application had been filed. This amendment would extend the term of certain Old Act patents to 20 years from the date the applications for these patents had been filed. Patents filed before 1 October 1989, however, whose 17-year term expires before clause 1 comes into force, would not be extended” (Smith 2001). In other words, Canada’s phase-in mechanism was offside of TRIPS but those patents whose 17-year term had already expired as of the coming into force date were not impacted and thus only enjoyed 17 years protection despite the WTO ruling. S-17 was assented to on June 14, 2001 and came into force shortly thereafter. Government of Canada, Privy Council Office, Orders in Council Database, accessed September 5, 2015, <http://www.pco-bcp.gc.ca/oic-ddc.asp?lang=eng&Page=secretariats&txtOICID=&txtFromDate=&txtToDate=&txtPrecis=&txtDepartment=&txtAct=An+Act+to+amend+the+Patent+Act+&txtChapterNo=&txtChapterYear=&txtBillNo=&rdoCodingIntoForce=&DoSearch=Search+%2F+List>

full protection that the US was pushing to become the global patent term standard under TRIPS. While this still reflected a win for US IP producers, it maintained some shelter for Canada's generic industry and drug insurance plans. The compulsory licensing framework in Bill C-22 effectively guaranteed 10 years of market exclusivity while simultaneously allowing Canada to cap protection at that level.

Bill C-22 ushered in the Patented Medicine Prices Review Board (PMPRB), a major policy innovation at the time, and marked the beginning of a long institutional response to increased patent protection. This provided many key innovations in the Canadian system that were directly aimed at mitigating the new IP regime for medicinal technologies. The PMPRB was a unique regulatory scheme internationally and positioned Canada on the leading edge of controlling patent pharmaceutical costs through international benchmarking. As noted by the PMPRB in its own call for policy renewal after nearly 30 years:

In 1987, when the PMPRB price referencing model was conceived, the concept of benchmarking domestic prices against prices in other countries was in its relative infancy. Today, price referencing is widely used in international price regulation but increasingly as an adjunct to other forms of cost containment. Between 2010 and 2012 alone, 23 European countries began planning or executed significant reforms to their pharmaceutical price regulatory framework to achieve greater cost savings (PMPRB 2015).

Benchmarking was successful for many years. As other countries also started benchmarking many added other cost-containment measures as part of their pricing and health insurance reimbursement regimes. The success of the PMPRB's mechanisms has been examined to some extent in the pharmaceutical policy literature and has been evaluated as a model for potential international policy export (Eastman 1994; Morin 2011). However, its specific model now seems somewhat out of date and there are many

calls to revisit its mandate to promote “affordability” or put downward pressure on prices as opposed to its strict legislated role of preventing “non-excessive prices” (Naylor et al. 2015, 30, 89, 91; PMPRB 2016). Nevertheless, the original legislation, Bill C-22, established a powerful institution and provided the Board with considerable scope for future reform.

Bill C-22 and the PMPRB

The government clearly anticipated that a powerful constraint to unbridled IP protections was needed. For example, the government considered and rejected the idea of industry self-regulation on the basis that it would not provide a sufficient guarantee of protection to the public.⁸⁸ There were several measures in Bill C-22 to constrain the impact of enhanced patent protections.

Bill C-22 included reporting requirements for prices in “any Canadian market” and costs of “making and marketing” such as research and development (Bill C-22 1987, 1187). This was an important provision for the government and public to ensure some transparency and monitor the pricing of patented technologies. Under the Act, information such as pricing provided to the Board by patentees was to be in a “form and manner and at such times and subject to such conditions as are prescribed” (Ibid, 1191). Much of the technical details of the provision of information were to be outlined in regulations and the Board’s own Guidelines. Where a patentee failed to provide information or “a medicine pertaining to a patented invention is being sold in any market in Canada at a price that in the opinion of the Board is excessive” the Board was empowered to order the patentee to reduce its price to a non-excessive level (Ibid, 1188).

⁸⁸ Canada Gazette, Part I, July 2, 1988 (2572).

In support of an excessive price determination the Board was directed in the *Act* to consider “to such extent as the Board deems reasonable” a range of factors including that product’s five-year pricing history (s. 41.15(5)a); prices of other medicines in the same therapeutic class sold in the market during the preceding five years (s. 41.15(5)b); international pricing for that medicine and others in its therapeutic class (s. 41.15(5)c); and the consumer price index (s. 41.15(5)d). In the event those four previous factors were considered but were not instructive in the determination of excessive price, the Board was empowered to consider the Canadian cost of making and marketing (s. 41.15(6)a) and “such other factors as are prescribed, or in the opinion of the Board, are relevant in the circumstances” (s. 41.15(6)b). More specific use of these factors was later incorporated into regulations and the Board’s Guidelines.⁸⁹

A key feature of the PMPRB not robustly addressed in the pharmaceutical policy literature is the fairly broad scope of its powers to interpret its legislated mandate. Bill C-22 arguably spelled out very little of how the PMPRB would come to its determination of “excessive pricing” and empowered the Board with considerable latitude for interpreting the excessive pricing factors outlined in the *Act*. The *Act* was really just the starting point for the establishment of the pricing regulator. Many of the most important technical details of the price control mechanisms were developed over time and did not appear in the initial legislative package. For example, the years 1989-1991—a period that the PMPRB has colloquially termed “Ironing Out the Details”—included many important discussions, consultations and policy refinements. These included: 1) the calculation of the Consumer Price Index adjusted methodology, or *how* allowable prices would be

⁸⁹ For a clear technical definition of how the Board defines ‘excessive pricing’ see page 16 of: PMPRB, (2015) “Compendium of Policies, Guidelines and Procedures,” version June 20, 2015, accessed July 5, 2015, http://www.pmprb-cepmb.gc.ca/CMFiles/LRG/Guidelines/Compendium-June2015_E.pdf

impacted by inflation; 2) supplementary guidelines on the Board's price review jurisdiction; 3) consultation on the methods used for determining excessive pricing; 4) how the PMPRB would address therapeutic class comparisons, or the currently marketed therapeutic comparators that would help benchmark the status quo pricing in a given clinical area; 5) international pricing comparison data sources for those countries already identified in regulation which would substantially impact allowable Canadian pricing; 6) policy regarding comparable dosage forms, for example, the strength and amount of active patented ingredients and how that should compare to other dosage forms; and perhaps most importantly, 7) the definitions and pricing tests used by the PMPRB for different categories or tiers of value ascribed to the patented technology, and thus, to what extent that technology reflected a scientific "breakthrough" (PMPRB Newsletter Volume 16, Special Issue No. 5, December 7, 2012).

These details and pricing tests were the sharp end of the PMPRB's regulatory spear. To have so many of these details largely subject to the pricing regulator's discretion was an important feature of the emerging institution that empowered it considerably and created room for future policy change. This is illustrated in the PMPRB's own framing:

Given the open-ended nature of the exercise contemplated under the legislation, many of the core administrative concepts which give effect to the PMPRB's consumer protection mandate have been developed through the Guidelines....While the factors in the Act are immutable (save amendment by Parliament), their open-ended nature allows for a flexible and contextually driven interpretation of excessive pricing under the Guidelines that evolves with time and changing circumstances (PMPRB 2016).

In contrast to the "ironing out the details" phase, the PMPRB framed the actual 1987 *Act* amendments and 1988 regulations as the phases of "creation" and "setting the stage,"

respectively (PMPRB Newsletter Volume 16, Special Issue No. 5, December 7, 2012). Clearly, the Canada-US compromise over the FTA and C-22 was only a starting point and Canada retained considerable regulatory autonomy and administrative flexibility despite the new patent rules.

Bill C-22 also specified the composition, appointment procedures, annual reporting requirements, and details related to tribunal hearings of the quasi-judicial body vested with “all such powers, rights and privileges as are vested in a superior court of record” (Bill C-22 1987, 1197). Provisions for Board Staff who came to play a central role in the work of the PMPRB were also referenced. In addition to Board Staff, the PMPRB would also establish the *Human Drug Advisory Panel* (HDAP) to recommend appropriate comparators from a scientific perspective for the therapeutic comparisons the Board was empowered to make under the amended *Patent Act* (PMPRB, *Human Drug Advisory Panel: Terms of Reference*, 2015b). This body was the primary mechanism through which the clinical benefits of a patented product were evaluated as a determinant of allowable price. This effectively created a regulatory system that evaluated the incremental clinical benefits of patented products and tied the maximum price of those products to the level of improvement provided over existing technologies.

The primary data considered in this evaluation process were the clinical trials used to support a product’s marketing authorization that were compared to the similar trial data for existing comparator technologies already on the market. This required HDAP’s membership to have considerable clinical expertise to make an assessment of comparative therapeutic advantages. Similarly, the PMPRB’s staff required considerable

economic expertise, as their role was to conduct the relevant pricing tests as informed by the HDAP clinical review. These pricing tests are discussed below.

Separating C-22 and its implementing regulation from the trade deal was an important win on Canada's part that allowed the PMPRB to grow and evolve as an entity separate from the FTA's commitments and implementing legislation. The *Act to implement the Free Trade Agreement between Canada and the United States of America*, was assented to 30 December 1988, just over three months *after* C-22's implementing regulations were adopted (Bill C-65, *An Act to implement the Free Trade Agreement between Canada and the United States of America*, 1988). This allowed Canada to demonstrate progress to the US on IP reform while maintaining considerable autonomy for future regulatory action. In other words, Canadian policy makers were able to secure a critical trade deal and fine-tune price control measures later in separate regulations and technical guidance. The trade-off for expanded IP rights in the form of limits to compulsory licensing and an extended patent term was a powerful new pricing regulator whose price controls would come to be a key object of discussion in the subsequent multilateral TRIPS negotiation (Interview with a Canadian official, December 5, 2015).

Two aspects of jurisdictional breadth further support the PMPRB as a powerful pricing regulator. The PMPRB would take a broad approach to the interpretation of its legislated jurisdiction and in 1996 the Federal Court of Appeal affirmed this view. The appeal court defined the PMPRB's jurisdiction as applying when there existed even a "slender thread of a connection" between a patent and a medicine.⁹⁰ This meant that the PMPRB could claim jurisdiction in essentially any case where a patent existed even if it

⁹⁰ *ICN Pharmaceuticals Inc and ICN Canada Ltd v. Canada (PMPRB)* [1996], *Federal Court of Appeal* 68 C.P.R. (3d), 417 – 441.

was a process patent only tangentially related to a product. The PMPRB's jurisdictional breadth was further entrenched by the Federal Court of Appeal who affirmed the PMPRB view that "a person need not own the patent over a particular medicine to be considered a 'patentee' in respect of that medicine within the meaning of subsection 79(1) of the *Patent Act*."⁹¹ The court held that the existence of a licence or an "implied" licence could infer PMPRB jurisdiction over a non-patent owner. Secondly, the PMPRB also claims "retroactive jurisdiction to the 'patent pending' period and will assert jurisdictions in the event of a patent dedication" (Critchley and Dietrich 2014, 56). Speaking in 2002, then Executive Director of the PMPRB, Wayne Critchley, noted that Board policy was that "once a patent is issued, its price review jurisdiction extends back to the date the patent application was laid open for public inspection" and as many as 18% of new drug products were launched on the Canadian market before the issuance of a first patent (Critchley 2002, 15). The PMPRB's logic here was that "because the patentee obtains the benefit to sue for reasonable compensation during the laid-open period, it also incurs the obligation to comply with the excessive pricing provisions" (Ibid).

PMPRB Implementing Regulation

Following Royal Assent of C-22 in November of 1987, the Government of Canada initiated a regulatory consultation.⁹² It received comments from five provinces, several pharmaceutical manufacturer associations and patent lawyers. Many of the comments related to the difficulty of establishing foreign prices for the purpose of comparison. The government noted that this was absolutely central to the PMPRB "fulfilling its mandate"

⁹¹ *Attorney General of Canada v. Sandoz Canada* [2015] *Federal Court of Appeal* 249, A-302-14 & A-303-14

⁹² Part I of the Canada Gazette July 2, 1988.

and thus no changes were made to the international requirements (*Patented Medicines Regulations* 1988, Canada Gazette Part II, SOR/88-474, 3955). The Canada Gazette II announcing the passage of this regulation by Order in Council reiterated the brand industry's commitment to double its Canadian R&D-to-sales ratio from 4.9% to 10% by 1996 (Ibid, 3956). Importantly for the PMPRB's capacity and future R&D investments, these targets were not in any way binding upon industry even though referenced in the regulatory package.

In September 1988 the Governor in Council, on recommendation of the Minister of National Health and Welfare, enacted the *Patented Medicines Regulations* (*Patented Medicines Regulations* SOR/88-474, 1988 Canada Gazette Part II, 3921).⁹³ The Regulations specified with greater precision what information patentees would be required to file with the PMPRB and included all of the detailed forms and paperwork to be filled out by the patentee for submission to the Board. The PMPRB regulates ex-factory prices: what the manufacturer charges customers prior to the application of any non-manufacturer mark-ups at the wholesale or pharmacy level. A primary feature of the regulations was to indicate the list of foreign comparators that the PMPRB would use for its calculation of "maximum non-excessive price." Manufacturers would be responsible for filing their prices in these countries with the Board.

The selection of comparator countries and pricing data (pricing sources) used in those countries was an important decision that would greatly influence allowable prices in Canada. The countries selected were Germany, France, Italy, Sweden, Switzerland, the United Kingdom and the United States. These were all justifiable comparators for

⁹³ The regulations were enacted November 15, 1988 with the full title "*Regulations Respecting the Reporting of Information Relating to Medicines and the Extent to Which Patented Medicines are Invented and Developed in Canada.*"

Canada, but only a subset of the 23 OECD countries that were apparently considered by policy makers (PMPRB 2015). According to the PMPRB, policy makers ultimately focused on these seven countries for aspirational reasons as they reflected high R&D investment jurisdictions.⁹⁴ The application of those international prices and the method of comparison was perhaps equally important. For example, it was consequential to patentee prices whether the Canadian maximum non-excessive price was tied to the international average, maximum, lowest, median or other pricing benchmark.

These important details were not specified in C-22. Also, the specific source of international pricing data was not specified at this time. It should be noted that prices within each international market can range considerably. The PMPRB's use of publicly available US "list" prices, which do not include confidential rebates and perhaps obscure actual average net prices, has been a flashpoint for criticism in recent years. Some argue that US pricing data should be excluded completely, or if used, US pricing should be established exclusively on the Federal Supply Schedule (FSS). This is the price that some US federal government drug plans pay and are typically much lower than US list prices published in the "Red Book."⁹⁵ Such an alternative comparison would force the Board's calculation of Canadian maximum non-excessive pricing down in many cases. As such, this is a common point raised by advocates of PMPRB reform who want to achieve lower

⁹⁴ "At the pre-publication stage of these regulations, policy makers initially proposed a more representative cross-section of 23 OECD countries for the Schedule; however, by the time of final publication, they opted for a more aspirational list in the sense that the selected countries had 'R&D expenditures at levels that we (Canada) intend to emulate'" (PMPRB 2015).

⁹⁵ The "Red Book" is a commercial publication of publicly available list prices and is one of the PMPRB's official price verification sources for the US market. PMPRB, "Recognized Sources for Foreign Price Verification and Formulas: 2015," accessed July 5, 2016, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1142>.

patented drug prices. The PMPRB eventually incorporated the FSS price as one source for average US price comparisons.⁹⁶

The 1988 *Patented Medicines Regulations* reiterated the objective of Canadian research and development (R&D) and clinical trials promotion. The regulations defined the “Extent to Which Medicines are Invented and Developed in Canada” as such:

A medicine is invented and developed in Canada if the major part of the inventing and the major part of the developing of the medicine to a marketable state have been conducted in Canada, including the major part of the design and control of Phase III clinical trials and, where possible, the major part of the conduct of Phase III clinical trials” (*Patented Medicines Regulations* 1988, Canada Gazette Part II, SOR/88-474, 3925).

The regulations articulated the mechanisms to assess this contribution in considerable detail. This included a definition of R&D that would come to be a source of future consternation with the patented pharmaceutical industry.

The regulations specified “‘research and development’ means those activities for which expenditures qualify, or would qualify if the expenditures were made by a taxpayer in Canada, for an investment tax credit in respect of scientific research and experimental development under the *Income Tax Act* as that Act read on December 1, 1987.” The industry would later contest that many of their investments made in Canada such as funding for venture capital and some expenditures on employment were not captured under the calculation and worked with the government to compile an alternative

⁹⁶ This was implemented in 2000. PMPRB NEWSletter January 2000, accessed October 25, 2015, http://www.pmprb-cepmb.gc.ca/CMFiles/News%20and%20Events/Speeches/NEWSletter_2000_1_Jan_E.pdf

calculation.⁹⁷ However, the R&D measurements would prove to be a satisfactory general metric. To date, this method for calculating R&D remains in place.

The promised benefits of enhanced R&D spending and the PMPRB as the new institutional mechanism to monitor these investments was part of an explicit bargain for limitations to the compulsory licensing regime and attempted to reflect balance between new IP rights and “protecting consumer interests” (*Patented Medicines Regulations* 1988, Canada Gazette Part II, SOR/88-474, 3952). The regulatory package noted the government’s intent of aligning Canada more closely with international patent norms; implicitly, those being championed by the US.⁹⁸ The 7 to 10-year limit on compulsory licences was not a full attempt at harmonization with US standards but did provide a major new advantage to the US drug industry.

As a limitation to this expanded market exclusivity, the PMPRB was “empowered to require corrective action by the patentee in respect of the selling price of the patented medicine or to direct that the product...of the patentee is no longer eligible for exclusivity” (Ibid, 3956). A Board order in this regard was not initially retroactive in the sense that the government could not reclaim excessive revenues accumulated by the manufacturer above the regulated price. The novel ability to order lower prices was a

⁹⁷ KPMG (2014) “Summary of 2013 R&D Spending and Investments by Rx&D Members,” June 13, 2014, accessed January 4, 2016, http://sharing.canadapharma.org/CMFiles/Our%20Industry/Industry%20Facts/2014-06-20_Rx&D_RD_Report_FINAL_EN.pdf). The steering committee for this alternative calculation of R&D conducted by the accounting firm KPMG included the PMPRB, the Canadian Institute for Health Research (CIHR), Rx&D (Brand Industry Association) and Industry Canada. By participating in this alternative accounting, the government implicitly acknowledged the shortfalls with respect to the PMPRB’s regulated R&D methodology. However, the regulations have not been changed perhaps due to the contentious politics of regulatory amendments in this area.

⁹⁸ “While the amendments to the Patent Act are based on a restriction of competition, such restriction is a normal aspect of the protection provided by the patent process. The amendments and these Regulations will improve Canada's competitive position in international pharmaceutical research and development by bringing Canada's patent protection in respect of pharmaceuticals more into line with that of other industrialized countries” (Canada Gazette Part II, SOR/88-474, 3954-5).

substantial power embodied in the new regulatory institution and set the stage for later expansion of PMPRB powers regarding retroactive revenues.⁹⁹

This regulatory flexibility is important to note. The introduction of the US Federal Supply Schedule (FSS) price is an excellent illustration of the PMPRB's general latitude in interpreting the regulations and powers to articulate this interpretation in its own Guidelines. From the beginning, the PMPRB Guidelines did not require that companies file FSS prices. In its argument for later inclusion of the FSS price, the Board cited its "view that the *Patented Medicines Regulations* require patentees to file publicly available prices listed in the U.S. [Department of Veterans Affairs (DVA)] formulary along with the other foreign prices filed." This interpretation was unassailable, despite considerable contestation from IP owners. But at the same time, there was nothing strictly forcing the PMPRB to include the FSS price in its calculation of the international price comparison, as the Guidelines had reflected since inception. The DVA formulary contained a couple of different price points—some lower than the FSS price—that were not used by the PMPRB as part of the new policy. The inclusion of the FSS price in the international price comparison was transitioned in over two years and precipitated price reductions in excess of 10% for only a small minority of cases.¹⁰⁰ However, the PMPRB technically could have chosen other lower prices on the DVA formulary. The point here is that throughout the implementation process, the Board retained considerable power in its application of the *Patent Act* and the more detailed regulations. Regardless of trade

⁹⁹ As discussed below, Bill C-91 implementing NAFTA's patent reform later granted additional powers to the PMPRB, in particular, to order the repayment by patentees of excess revenues derived from the sale of a medicine at an excessive price (Bill C-91 1993, 18).

¹⁰⁰ *Ibid.*, 2.

commitments, Canada maintained considerable autonomy and future flexibility when implementing them.

1989–1991: “Ironing out the details” and the Excessive Price Guidelines

As discussed, implementation of the PMPRB’s price control function was centrally articulated in regulations and the drafting of its Excessive Price Guidelines as the *Act* only identified broad factors the Board should consider in its determination of excessive price. Consultation on the Guidelines commenced in 1988 and its first iteration was published in July of that year. The Board defines its Guidelines as providing “transparent predictable guidance to patentees on the approach Board Staff uses when determining whether prices of patented medicines are excessive... Even though the Guidelines are not binding on the Board... [it] considers the Guidelines an articulation of the methodology used in applying the factors in the Patent Act” (PMPRB 2006, 3). The Board has exclusive jurisdiction over the Guidelines and in the few instances when it has made substantial changes to them has engaged in robust consultation with provincial Ministers of Health, manufacturers, patients and physician groups.

The *Excessive Price Guidelines* are important because they articulate the methodology and analytical tests used to tie the allowable price of a patented product to its comparative therapeutic value over existing products. For example, the Board would reward a “breakthrough” or “substantial improvement” product a higher price than those with only a “modest improvement” or those essentially equivalent to existing technologies. Breakthrough or Category 2 patented technologies were granted the international median price for that same product, often at a premium over Canadian prices in that drug class. Drug products providing “moderate, little or no therapeutic

advantage over comparable medicines” or Category 3 drugs were granted a maximum non-excessive price according to a “Therapeutic Class Comparison” (TCC) test. This compared “the price of the new patented drug product to the prices of other clinically equivalent drug products used to treat the same disease, and sold in the same markets” as identified by the Human Drug Advisory Panel (PMPRB 2006, 8-10).

As the name suggests, this Therapeutic Class Comparison (TCC) test helped to hold prices for drugs with only marginal improvements to a price comparable to existing products in the same therapeutic area. Category 1 products, which included new strength or dosage forms of an existing medicine, would be priced according to a “reasonable relationship” test, which would ensure that minor modifications to marketing or dosing forms¹⁰¹ did not result in any premium price (Ibid, 9-10). Figure 3.1 summarizes the pricing tests and thresholds used by the PMPRB in its early Guidelines. For information, ANNEX A summarizes the rules as modified to provide additional categorical specificity.¹⁰²

Figure 3.1: PMPRB Pricing Categories and Associated Tests, as of July 1989¹⁰³

PMPRB Category Definitions	Allowable pricing test and PMPRB Definitions
One - drug products are a new strength (e.g., 50 mg v. 100 mg) or a new dosage form (e.g., tablet v. capsule) of an existing medicine	Reasonable Relationship (RR) test: considers the association between the price of the new strength of the existing medicine and the prices of other strengths of the same medicine in the same or

¹⁰¹ Dosage forms are the final preparation that includes an active pharmaceutical ingredient. “Dosage forms include, among other groups: oral solid (e.g., capsule, tablet, caplet); oral liquid (e.g., drops, solutions, powders for solution or suspension); topical (e.g., aerosol, cream, patches, powder) etc” (Ibid, 10).

¹⁰² New rules with additional details on each regulatory category became effective January 2010. As is typical of Guidelines amendments, this followed an extensive stakeholder consultation that began in May 2006.

¹⁰³ Originally released in July 1988 and amended in July 1989. PMPRB. 2006. Discussion Guide for the Consultations on the Board’s Excessive Price Guidelines. Accessed January 3, 2016 <http://www.pmprb-cepmb.gc.ca/cmfiles/consultations/BoardsExcessivePriceGuidelines/DisGuide-e38LSN-1262006-7439.pdf>

	comparable dosage forms
<p>Two - a breakthrough or substantial improvement over existing medicines</p> <p>A breakthrough drug product is the first one to be sold in Canada that effectively treats a particular illness or effectively addresses a particular indication.</p> <p>A substantial improvement is one that, relative to other drug products sold in Canada, provides substantial improvement in therapeutic effects (such as increased efficacy or major reductions in dangerous adverse reactions) or provides significant savings to the Canadian health care system.</p>	<p>International Price Comparison (IPC) test: compares the average transaction price of the new patented drug product with the publicly available ex-factory prices of the same dosage form and strength of the same medicine sold in the countries listed in the regulations (France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S.).</p> <p><i>Median of the International Prices (MIP)</i> test: is mainly used for category 2 drugs but may also be applied to category 3 drugs when it is impossible or inappropriate to identify comparable drugs in Canada.</p>
<p>Three - moderate, little or no therapeutic advantage over comparable medicines</p>	<p>Therapeutic Class Comparison (TCC) test: compares the price of the new patented drug product to the prices of other clinically equivalent drug products used to treat the same disease, and sold in the same markets at a price that the Board considers not to be excessive.</p> <p>In the context of a TCC test, the price of a new medicine is considered excessive if it exceeds the highest price of the therapeutically comparable drugs in Canada.</p>

At the time of the Guidelines' establishment, there was considerable controversy over what formula to use, specifically for the international price comparison. The price determination factors in the *Act* directed the Board to consider the price that the medicine is sold at in other countries. Industry "considered the median an arbitrary and inflexible measure having inherent statistical problems of measurement" whereas others thought that "Canada should not be expected to contribute at a premium" pricing level (PMPRB 2006, 17). While the Board technically had the power to use the minimum price, or some

other average price, it resisted opposition to the international median price for breakthrough products. It deferred to the *Act* to justify the use of international pricing benchmarks in general terms, and did not bow to the pressure of industry over the specific issue of the median (Ibid). Again, this feature was a product of an implementation process that was light on details and allowed officials considerable latitude following legislative implementation.

US industry also took issue with the Therapeutic Class Comparison (TCC) and noted it would put downward pressure on pricing, for example, in cases where a low priced generic drug was the only drug in a therapeutic category. In its justification for keeping the TCC test, the PMPRB noted a key provision in the *Act* that “does not differentiate patented medicines from non-patented or generic medicines” (Ibid). Thus in the Board’s view the comparison to lower priced generics was justifiable in some cases even if it was the only comparable marketed product. Taken together, this is a good illustration of how the Board uses its flexibility at some times but also leverages the more rigid elements of its legislated constraints both in service of its consumer protection mandate.

In addition to pricing regulation on introductory prices at product launch, price increase controls according to changes in the consumer price index (CPI) were introduced. The *Patent Act* amendments mandated that CPI is one factor that the PMPRB must consider. The Board has interpreted this such that patentees cannot typically increase prices in excess of inflation. The CPI methodology outlined in the Guidelines has been subject of debate and refinement over the years. However, the core function to

cap price increases for patent products has remained. The 1989 version of the Guidelines spelled out the technical details of the Board's CPI methodology:

the price of a [drug identification number (DIN)] at the time of a review (the current price) will be compared with the benchmark price of the medicine adjusted for the cumulative change in the Consumer Price Index (CPI-adjusted price). Where the current price of the DIN is greater than the CPI-adjusted price, the current price will be presumed to be excessive unless there is significant evidence to the contrary (PMPRB, *Price Increases for Patented Medicines: Discussion Paper*, 2005).

In other words, normally CPI would bound the upper limit for price increases but the Board empowered itself with some discretion over justifiable exceptions. This CPI component has added a price stability component to the PMPRB's impact over patented medicines, which is a key difference from the more market-based US system where price increases for patented and even non-patented drugs are sometimes an issue.¹⁰⁴ US stakeholders often cite Canada's system of price control as a potential model even though it is not always understood that the PMPRB only regulates *patented* products and non-patented drug prices are regulated to various degrees by provincial governments that have constitutional responsibility for "property and civil rights" under section 92(13) of the *Constitution Act*, 1867. In fact, the constitutional authority of the PMPRB to regulate prices of patented drugs has been subject to challenge¹⁰⁵ and the courts have validated the

¹⁰⁴Andrew Pollack "Drug Goes From \$13.50 a Tablet to \$750, Overnight" *The New York Times*, September 20, 2015, accessed December 18, 2015, <http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?smid=tw-nytimes&smtyp=cur&r=0>

¹⁰⁵In response to a PMPRB hearing, one company sought a court order "Declaring that sections 83 through 86 of the Patent Act R.S. C. 1985, ... are ultra vires the Parliament of Canada in that the price regulation scheme created by the impugned provisions exceeds the powers granted to Parliament under s. 91(22), or other federal power, of the *Constitution Act*, 1867 and improperly intrudes into provincial jurisdiction over property and civil rights in the province under S. 92(13) of the *Constitution Act*, 1867" *Alexion Pharmaceuticals v. Patented Medicine Prices Review Board and Attorney General of Canada*. "Notice of Application Under Sections 18(1)(a) and 18(1)(b) of the *Federal Courts Act*" T-1537-15. Accessed September 26, 2015, <http://s3.documentcloud.org/documents/2431416/alexion-federal-court-filing-sept-11-2015.pdf>. The Federal Court dismissed this constitutional challenge in June 2016.

Board's jurisdiction on numerous occasions (PMPRB 2016). This included the validation of the Board's "consumer protection" mandate by the Supreme Court of Canada.¹⁰⁶

CPI was also an important metric for Canada's *transition* to regulated prices. One of the policy issues that the Board had to consider was if and how to apply its pricing methodology to products already on the market. Immediate implementation of the TCC and even the more generous median test would have likely had a substantial impact on prices and faced considerable backlash from manufacturers and the United States. The PMPRB decided to apply those more restrictive tests to new products and use CPI to cap future prices for existing marketed products. The Board leaned on the *Act* to justify this decision: "After careful consideration of the factors in the *Act* to be used in determining whether a price is excessive, the Board decided that it was reasonable to place the greatest weight on the Consumer Price Index (CPI) factor in assessing the prices of existing medicines and to establish the benchmark price as the selling price on December 7, 1987" (PMPRB 2006, 16). Per this transition measure, the Guidelines' therapeutic pricing tests would not be retroactive but price *increases* would be controlled going forward. The effect of this was to delay the full impact of the Guidelines somewhat. While there were immediate impacts for new patented products, it was not until 1994 that aggregate average prices actually fell below the international median of prices (Government of Canada 1997, 14, 19).

¹⁰⁶ Celgene Corp. v. Canada (Attorney General), 2011 SCC 1, [2011] 1 S.C.R. 3, accessed August 28, 2015, <https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/7913/index.do>. In this case the Supreme Court held: "The Board's interpretation of its mandate under the relevant provisions was consistent with its consumer protection purpose and should not be disturbed. The Board is responsible for ensuring that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian consumers. While words like "sold" may well have a commercial law meaning in some statutory contexts, accepting a technical commercial law definition in this context would undermine the Board's consumer protection objectives by preventing it from protecting Canadian purchasers of medicine."

The combination of therapeutic benchmark pricing and CPI pricing controls would ensure that pricing in Canada was tied to a patented product's value, and that average Canadian prices (adjusted for exchange rates) were typically lower than many international prices. According to the PMPRB:

In 1997, 78% of patented drug products were priced below the median international price in Canada; in 1987, only 45% were priced below the median international price. By 1997, prices for patented drugs in Canada had come down relative to the seven other countries in the basket. In 1987, Canada had the highest price in over 21% of the cases, but this had dropped to less than 2% of the cases in 1997 (PMPRB 1998, "Road Map for the Next Decade," 22-3).

This pricing differential had international political implications, particularly for Canada-US relations. Given that drug prices were considerably lower in Canada as a result of pricing regulations and exchange rate factors a drug "reimportation" industry emerged where US citizens increasingly sought to purchase their drugs from Canada. Reimportation refers to products supplied by US companies to the Canadian market that are then sold back into the US market at lower prices than paid by other US customers. This bilateral irritant has ebbed and flowed in recent decades and often resurfaces during periods of Canadian dollar depreciation. Drug reimportation is prohibited in the US but the practice has nevertheless proliferated under a personal use exemption (Drabiak 2005, 139).

Critics of high US drug prices have most recently reinvigorated this debate led by Senator Bernie Sanders, who introduced the *Prescription Drug Affordability Act of 2015*. The Bill would facilitate the reimportation of drugs from Canada.¹⁰⁷ Sanders even

¹⁰⁷ Bernie Sanders, Draft Bill "*Prescription Drug Affordability Act of 2015*" accessed January 3, 2016, <http://www.sanders.senate.gov/download/text-of-prescription-drug-affordability-act-of-2015?inline=file>

highlighted a 1999 trip he took as “the first member of Congress to take Americans across the border to purchase lower-cost drugs in Canada.”¹⁰⁸ Presidential candidate rival Hillary Clinton similarly highlighted reimportation in her campaign plan for *Lowering Prescription Drug Costs*.¹⁰⁹ Reimportation and Canada’s market remains attractive to advocates of US drug reform largely due to the combination of favourable exchange rates and the price controls of the PMPRB.

In summary, Canada established a new pricing institution for patented products with broad, open-ended powers in the context of implementing its FTA. This institution would substantially mitigate the effect of IP reforms. The following section examines the evolution of the institution to address additional IP protections under TRIPS and NAFTA and shows how the preservation of price regulation institutions helped to shape those negotiated outcomes.

Adoption of the Draft TRIPS in NAFTA

This section argues that an important Canadian goal of the international negotiations was to preserve the PMPRB’s capacity to regulate. The PMPRB was a key component of the domestic sales pitch for NAFTA’s IP reforms and was significantly strengthened in the NAFTA context. The section also argues that timing and sequencing of NAFTA and TRIPS were important factors in the ultimate negotiated outcomes, and perhaps the ultimate conclusion, the Uruguay Round and TRIPS. Power, existing institutions, and

¹⁰⁸ Omar el Akkad, “Drug price hikes are not a new trick” *The Globe and Mail*, September 28, 2015, accessed January 3, 2016, <http://www.theglobeandmail.com/report-on-business/international-business/us-business/drug-price-hikes-are-not-a-new-trick/article26556801/>

¹⁰⁹ Hillary Clinton for President. “Hillary Clinton’s Plan for Lowering Prescription Drug Costs” accessed January 3, 2016, <https://www.hillaryclinton.com/p/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs/>

historical sequencing of agreements are all required to understand the NAFTA/TRIPS outcome on intellectual property.

While the impacts and regulatory feedbacks of Bill C-22 were playing out in Canada, negotiations in Geneva on the Uruguay Round and TRIPS continued on much of the same subject matter. Canada's 1987 limitation on compulsory licences actually reflected a considerable policy accomplishment by the generic drug sector given that qualified abolishment was clearly imminent and Canada's Progressive Conservative Government under Prime Minister Brian Mulroney explicitly preferred this option. The position was manifest in early submissions Canada made in October 1989 on the General Agreement on Tariffs and Trade's (GATT) TRIPS negotiations. Canada supported compulsory licences only under certain circumstances:

Compulsory licensing should be available to parties only under certain limited conditions and in accordance with the Paris Convention. This Convention contains certain safeguards but is not sufficient. In particular, it does not require adequate compensation or access to judicial review. Accordingly, the legitimate public interest purposes for which compulsory licensing could be required by participants to a TRIPS agreement should be defined. In addition, important safeguards should be provided in order to protect the rights of the patentee in terms of: [In bulleted list] Full transparency; National Treatment; Non-exclusivity; Adequate compensation; Judicial review (Government of Canada, 1989a, MTN.GNG/NG11/W/47 October 25: 6).

Judicial review was an important element of Canada's submission that would provide a patent owner the ability to challenge any compulsory licences issued. This would affirm the power of domestic courts to have the final word on interpreting whether granted licences complied with TRIPS exceptions to exclusive use (i.e. acceptable compulsory licences). The excerpt also supports a central contention of this study that trade agreements and IP regulation are historically cumulative and agreements typically build off of and address issues with past treaties, in this case, both the Paris Convention and

Canada's earlier commitments on compulsory licences. International regulatory positions are shaped by history.

On patentable subject matter, Canada called for explicit reference in TRIPS given that the Paris Convention did not address this. Canada also provided its favoured definition:

The [Paris] Convention is silent with respect to patentable subject matter, necessary conditions for obtaining a patent and term of protection and it deals only marginally with the rights conferred by a patent. Accordingly, Canada considers that significant improvements should be added to those standards in the Paris Convention, and that these should be developed as part of a TRIPS agreement...Patents should be available under the first to file principle. Patents should be available for inventions that are new, useful and unobvious (Government of Canada 1989a, MTN.GNG/NG11/W/47 October 25: 6, 11).

This shows that Canada was attentive to the issue and importance of the definition of patentable subject matter that would come to be an issue in subsequent patent utility litigation (discussed in Chapter 5). Canada did not propose a definition of "useful" at this time and there were no references to utility as being linked to industrial application as contained in the final TRIPS text. TRIPS reads "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application" (TRIPS 1994, Article 27(1) *Patentable Subject Matter*). Canada's GATT submission on TRIPS refers at least five times to where "National laws" should prevail and its proposed definition of patentable subject matter would leave considerable latitude for national courts to interpret the terms "new, useful and unobvious."

Canada also submitted a separate position on TRIPS *enforcement*. This similarly encouraged national flexibility and general international harmonization of enforcement

standards, while not necessarily creating identical systems: “a TRIPS agreement should recognize that individual participants will want to maintain reasonable flexibility in the application of basic international enforcement obligations within their own national legal systems” (Government of Canada 1989, MTN.GNG/NG11/W/42 September 5: 2). Canada appears to have been keenly aware of protecting sovereignty as part of the TRIPS Agreement. It also wanted to assure “reasonable” but not “excessive” compensation to inventors and balance this “against the rights of the public-at-large to reasonable access to the innovation/creation at reasonable prices and to legitimate access for such purposes as research and education” where rights are granted *by* the government “representing the broad interests of the public-at-large” (Government of Canada 1989a, MTN.GNG/NG11/W/47 October 25: 4). This language regarding balance and a public bargain would resurface throughout Canada’s history of intellectual property legislation and litigation (see chapter 5).

Senior officials commenced negotiation on the North American Free Trade Agreement in Toronto on June 18, 1991 with intellectual property as one of six broad areas established by the senior negotiators. From the outset, the model established in the bilateral agreement between Canada and the United States in 1987 formed the basis of negotiations (Cameron and Tomlin 2000, 82). As noted by one Canadian official, “the whole concept of NAFTA came out of the fact that we already had a free trade agreement with the United States” (Interview with a Canadian official, December 15, 2015). This follow-on agreement to the FTA took many of the IP provisions negotiated but not published in the FTA one step further. Canada initially resisted further change to its compulsory licensing regime beyond what was agreed to under the FTA and Bill C-22.

However, by December 1991 the General Agreement on Tariffs and Trade (GATT) Uruguay Round's negotiators had reached a draft of TRIPS contained in the "Dunkel Text"¹¹⁰ that would effectively prohibit most compulsory licensing. Canada's then Trade Minister Michael Wilson indicated that Canada would accede but positioned that Canada would not stray too far from the TRIPS draft in NAFTA (Cameron and Tomlin 2000, 97, 104). The adoption of TRIPS effectively neutralized much of the negotiation regarding intellectual property as part of NAFTA and Canadian negotiators centrally focused on exemptions from free trade for cultural products that Canada was ultimately able to secure (Ibid).

The timing and sequencing of NAFTA and TRIPS were major factors in the ultimate negotiated outcomes, and perhaps the ultimate conclusion of a Uruguay Round that included TRIPS. On intellectual property, NAFTA largely replicated what had already been negotiated, but was yet to be formally agreed upon in the multilateral context. With the Uruguay Round stalled in 1992-3 over agricultural issues, the trilateral NAFTA deal was seen as a pump-primer¹¹¹ to help drive the Uruguay Round to finalization. According to one Canadian official:

at that point the Uruguay Round was stalled...The whole purpose of NAFTA was to give the Uruguay Round some impetus or at least convince others, that, see, we can do it trilaterally, so you better do that for the world. And so it only seemed natural to sort of almost mirror the Uruguay Round [TRIPS] in some ways...The interesting thing about NAFTA is although it looks like it came first, it in fact came second...and you will notice that NAFTA is almost word for word, 90

¹¹⁰ The Dunkel text was an early Draft of the multilateral trade agreement named for GATT Director-General Arthur Dunkel. *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, GATT Doc. No MTN.TNC/W/FA (Dec. 20, 1991), accessed September 13, 2015, https://www.wto.org/gatt_docs/English/SULPDF/92130093.pdf

¹¹¹ As discussed above, the pump-primer metaphor reflects an intentional action that acts as a source or impetus for some related action. The term pump-primer is used here to describe the role NAFTA played in helping to provide an impetus to finalize the multilateral Doha Round of trade negotiations.

percent, what's in the TRIPS Agreement. And that's because the TRIPS Agreement had already been largely settled by the time NAFTA really started...So clearly it was the view of all three participants, that having negotiated hard for the last two-and-a-half, three years in Geneva, it didn't make much sense to re-invent the wheel...and as a result you will see that a lot of the language in the TRIPS Agreement, is in fact, what's in NAFTA. Now ultimately NAFTA came first because...the Uruguay Round had an agricultural issue that had to be resolved, and that didn't get resolved until after NAFTA. In fact, the Americans would claim that having...signed NAFTA is what gave impetus to conclude the Uruguay Round. In the TRIPS context, most of the TRIPS and certainly, most of the patent stuff, had already been agreed among [Canada, US, Mexico], and the most difficult one in the Uruguay Round context, among the three of us...was obviously compulsory licensing. And that language on compulsory licensing had already been agreed in the TRIPS Agreement (Interview with a Canadian official, December 5, 2015).

This account is consistent with the historical institutionalist notion that the sequencing of events can be a determinant of international and domestic regulatory regimes. As a matter of practicality, NAFTA's IP content was largely determined by TRIPS. TRIPS, while largely resolved from a negotiation perspective, required considerable impetus to be finalized from a political perspective and NAFTA was central to that legitimization strategy. Market power was perhaps a necessary but not sufficient condition to finalize Uruguay and TRIPS. Legitimation through NAFTA seems to have been a key precursor.

The final GATT and TRIPS negotiated outcome published for party signatures on April 15, 1994 also largely reflected the Dunkel text of December 1991 (Dwyer 1999, 221). A change of power in Washington following the November 1992 election saw President Clinton's administration adopt a strong multilateral liberalization agenda and resume GATT Uruguay Round negotiations. These had previously been launched in 1986 under the Reagan administration, but were extensively negotiated under the George H.W. Bush administration. However, there was a considerable stalling of the Uruguay Round

as the Clinton administration in 1993 prioritized passing NAFTA through Congress and sought changes to the Dunkel draft with respect to TRIPS in response to calls from business sectors including semiconductors, music, film, and pharmaceuticals. The pharmaceutical industry wanted TRIPS patent protection to apply for products in their current research “pipeline” and shorter transition periods for developing countries to phase in developed-country standards than those that were provided in the Dunkel draft. Pipeline protection referred to policy that would essentially provide TRIPS patent provisions to drugs that had already been patented but were still in the research phase of development and had not yet been marketed when TRIPS came into effect (Dwyer 1999, 515, 518, 533).

Such concerns were not simply minor obstacles associated with a fringe US business constituency. The US “knowledge economy” and service sectors were incredibly important to the negotiations and perhaps the very existence and future of the US multilateral agenda. Before Canada’s Parliamentary Trade Committee, eminent trade scholar and former Canadian official Dr. Sylvia Ostry discussed, at length, the impact of those sectors and the undergirding political dynamics:

The last round of the Uruguay Round was unique in that it is unlikely that the United States would have maintained its commitment to the multilateral system without the support, and the active support, of the American business community. The reason for that is many in the United States believed it was easier, since they were a superpower, to get things unilaterally or bilaterally. If you're powerful you can use aggressive unilateralism or bilateralism, so why do you need this cumbersome international rule-based system in Geneva?

The administration was worried about that, and rightly so, since in the mid-1980s there was an enormous protectionist surge in Congress stemming from Reaganomics, from the growing deficit and the overvalued dollar. Indeed, I would argue that this is why we had the [Canada-US] FTA. It was an insurance policy, because we [Canada]

would have been killed if any of those 114 bills [protectionist bills proposed in US Congress] had come through.

What happened was that there was an amazing rallying of the business community, both in the intellectual property and in the service area, which said to the administration, if you can deliver these new issues, as they were called—services, intellectual property, and investment—we'll deliver the multilateral support, which they did. They organized coalitions, dragging the Japanese Keidanren [Japan Business Federation] in, the European business round table, and so on. Their deal was, we want the new issues and we'll support the multilateral system. That's in fact what happened (Ostry, Standing Committee on Foreign Affairs and International Trade, Tuesday, April 27, 1999, at 0920).

To summarize, US internal politics and the legacy of Congressional isolationism provided the IP and services industries with an enormous opportunity for alignment with the US executive branch and a vital source of support for the GATT Uruguay Round. “New issues” such as intellectual property and investment protections were a driving force in those multilateral agreements. Intellectual property had in fact been one of the original 15 Uruguay Round subjects at the launch of that round in 1986.

While the overarching interest and support was critical, it is important not to overstate the ability of this corporate power to translate into specific desired outcomes in every instance. All negotiations conclude with some compromises. For example, after considerable discussion of the Dunkel text, the US pharmaceutical industry did not ultimately achieve so called “pipeline protection” in TRIPS. NAFTA, namely 1709 section 4, was thus in some ways more protective than TRIPS: “Given that ‘pipeline protection’ had been secured in the NAFTA agreement, the U.S. pharmaceutical industry was dismayed by their inability to have the same protection in the TRIPS [A]greement” (Dwyer 1999, 534-535, 568). The lack of pipeline protection for pharmaceuticals in the final TRIPS Agreement was apparently part of a trade-off made by the Clinton

Administration for modified compulsory licensing provisions requested by the semiconductor industry in the form of more restrictive (fewer) exceptions to compulsory licensing specific to those technologies (Dwyer 1999, 528, 536).¹¹² In exchange for this concession to Silicon Valley, the USTR essentially abandoned its positions on pipeline protection and shorter transition periods for developing countries despite a strong lobbying effort by the US pharmaceutical industry (Ibid).

NAFTA also went further than TRIPS in terms of offering a specified period during which data used in the application for a marketing approval would be protected. TRIPS only specified that confidential data submitted to a regulator would be protected against “unfair commercial use” (TRIPS, Section 7: Protection of Undisclosed Information, Article 39(3)). By contrast, NAFTA specified that no other manufacturer could “rely on such data in support of an application for product approval” during a period of “not less than 5 years from the date on which the Party granted approval to the person who produced the data” (NAFTA, Article 1711: Trade Secrets, Section 5-6). This “data protection” was “a NAFTA innovation” in that it had never before been incorporated into a trade deal and was thus a “ground breaker” for international IP negotiations (Interview with a Canadian official, December 5, 2015).¹¹³

It is perhaps not surprising that the IP protections (pipeline protection and data protection) in NAFTA went slightly further than TRIPS despite Canadian ministerial declarations to the contrary. Likely due to its pump-primer status and negotiation

¹¹² TRIPS Article 31 “Other Use Without Authorization of the Right Holder” section C, “Scope and duration” differs from its sister provision in NAFTA Article 1709 “Patents” Section 10(C) “Scope and duration” in that it specifies licenses for semi-conductors as only for “public non-commercial use” or to remedy anti-competitive practices as determined by judicial review (NAFTA 1993) (TRIPS 1994).

¹¹³ It would have a major impact on future trade negotiations such as the Trans-Pacific Partnership where this period of data protection for biologic drugs would feature prominently in the talks.

dynamics, the US appears to have been willing to offer more in NAFTA to get that deal done than it was willing to offer all countries in the Uruguay Round context and TRIPS. The issue of data protection was in fact negotiated in both agreements but the US was only able to “pay enough” for it in the NAFTA context:

There were a number of things that were included in NAFTA... which weren't included in TRIPS, and that's because there was a number of things that, well first of all, the dynamics of NAFTA were somewhat different, and the price paid for them were somewhat different...in the context of the TRIPS negotiations there was pretty much an overwhelming opposition, including from Canada by the way, [to] pipeline protection...and as a result... you could say that the American's couldn't pay enough for it... that may be an appropriate way of thinking about it in the negotiating context...

There were things that Canada paid [for] in NAFTA that it didn't get in the Uruguay Round, which were very important from a Canadian perspective, and ultimately.... what that means in a negotiating context [is] one tends to put a price on the number of concessions. And in the context of the Uruguay Round that price was not met, but in the NAFTA context it was.

... [Data protection] was debated in TRIPS too...it was kind of like the pipeline stuff...it was a concession that Canada was willing to make in NAFTA but not willing to make in TRIPS... and partly 'cause a) we were in really good company in TRIPS and b) because [there were] additional concessions that were being made in NAFTA that weren't being made in the Uruguay Round (Interview with a Canadian official, December 5, 2015).

In other words, the US was highly intent on seeing NAFTA settled with strong IP protections and was willing to incentivise that agreement to go further on IP than the draft of TRIPS as it was negotiated to that point in time.¹¹⁴ It is reasonable to infer that the “price” paid by the US on NAFTA reflected its importance as a precursor to the

¹¹⁴ Linking trade to IP reforms within a treaty was a long-standing US goal. As noted by FTA-negotiators in a comprehensive book on those talks the “US interest in intellectual property was driven by broad policy concerns and a desire to demonstrate to the world the feasibility of including intellectual property in a trade agreement... [t]hey also wanted to resolve the long-standing pharmaceutical.... issues in the context of an intellectual property package” (Hart, Dymond and Robertson 1994, 306).

multilateral deal. Here again we see a balance between market power and temporal considerations related to NAFTA as a pump-primer agreement. Knowledge of both power and the sequencing of agreements is required to understand the outcome on intellectual property.

Bill C-91 1993: Regulatory Institution Strengthened in Response to NAFTA

As Canada's intellectual property regime transitioned to be NAFTA and TRIPS compliant, past policy choices such as compulsory licensing and regulatory pricing controls continued to have a powerful institutional legacy and shaped the regime going forward. Canada's existing institutional system even helped to shape *international* regulatory standards as Canada acted to preserve the capacity of its domestic price control institutions to constrain the impact of expanded IP protections. This section explores these dynamics.

Many of Canada's NAFTA and TRIPS intellectual property commitments were implemented through Bill C-91, the *Patent Act Amendment Act, 1992*, which received Royal Assent on February 4, 1993 (published in Canada Gazette III, Vol 16 (1), May 10, 1993). This was the last piece of major legislation passed before the February 24, 1993 announcement of the resignation of Prime Minister Brian Mulroney amid extremely low popular support after eight and a half years of power.¹¹⁵ One key provision in C-91 was to repeal section 39 of the former *Patent Act* enabling compulsory licensing.¹¹⁶

¹¹⁵ CBC Digital Archives (1993) "Brian Mulroney steps down," accessed December 12, 2015, <http://www.cbc.ca/archives/entry/brian-mulroney-steps-down>

¹¹⁶ The *Patent Act* as it read in 1992 contained the following text that was amended by C-91: Section 39 (4) *Licence under patent relating to medicine* "Where, in the case of any patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine, an application is made by any person for a licence to do one or more of the following things as specified in the application, namely, (a) where the invention is a process, to use the invention for the preparation or

Article 31 of the TRIPS Agreement, entitled *Other Use Without Authorization of the Right Holder* is the provision that effectively prohibits broad granting of compulsory licences for patented products. As noted by a position paper on the WTO website the actual term “compulsory licensing” is not specified in the TRIPS Agreement and there are multiple exceptions to the prohibition including “national emergencies,” “other circumstances of extreme urgency” or “public non-commercial use.”¹¹⁷ In other words, TRIPS permits compulsory licensing only in certain situations and even ensures compensation to patent holders. However, much of the language regarding those exceptions is ambiguous (Ford 2000, 959, 963). This ambiguity allows for some latitude with respect to national interpretation. Beyond those exceptions, however, the impact of Article 31 is a general prohibition on compulsory licences.

For practical purposes, TRIPS would prevent a signatory government from granting licences in support of a domestic commercial interest or strictly for cost-containment purposes. As noted above, compulsory licences had previously been used in Canada to limit public health expenditures on patented pharmaceuticals, and in doing so, supported the development of the Canadian generic pharmaceutical sector. TRIPS would thus require substantial change to Canada’s compulsory licensing regime limited earlier under Bill C-22. Canada did, however, build in two exceptions to patent infringement that would help to soften the removal of compulsory licences.

For obvious reasons, Canada’s generic pharmaceutical industry was vehemently

production of medicine, import any medicine in the preparation or production of which the invention has been used or sell any medicine in the preparation or production of which the invention has been used, or (b) where the invention is other than a process, to import, make, use or sell the invention for medicine or for the preparation or production of medicine, the Commissioner shall grant to the applicant a license to do the things specified in the application except such, if any, of those things in respect of which he sees good reason not to grant a licence.” (*Patent Act* as it read in 1992, as cited by: Zischka, Ing and Chung 2012, 28).

¹¹⁷ WTO, (2006) “TRIPS and pharmaceutical patents,” Online Fact Sheet September 2006, accessed September 10, 2015, https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

opposed to the abolition of compulsory licences and according to one Canadian official, these were among the most contentious parts of the TRIPS resolution (Interview with Canadian official, December 5, 2015). In response to generic industry concerns, the government noted the sector had prospered despite the passage of Bill C-22, growing 180% between 1987 and 1992.¹¹⁸ Canada's TRIPS and NAFTA accession was a major policy loss for the generic industry. However, during the implementation process via Bill C-91, the generic industry was able to secure two important concessions. The first was a so-called "early working" provision that allowed manufacturers to develop generic products during the patent period. This appeared prominently at the beginning of C-91, Section 55.2 (1):

It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product (Bill C-91, Canada Gazette III, Vol 16 (1), May 10, 1993).

This implementation manoeuvre by Canada was designed to advance the interests of its generic industry. Manufacturers could work towards product approval during the patent period and would be ready to compete in the market at the moment of patent expiry.

The second measure was a so-called "stockpiling" provision which was designed with a similar objective to facilitate immediate generic market penetration. Section 55.2 (2) provided that:

It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture

¹¹⁸ Michael Wilson, Third Reading of Bill C-91, House of Commons Debates, December 10, 1992, 15021, accessed October 15, 2016, http://parl.canadiana.ca/view/oop.debates_HOC3403_12/219?r=0&s=1

and storage of articles intended for sale after the date on which the term of the patent expires” (Ibid).

This implementation manoeuvre allowed generic manufacturers to mass-produce and store drug products in their Canadian and international facilities to immediately flood the market upon patent expiry or a successful legal challenge of a patent.

Neither of these measures were part of the Dunkel Text, NAFTA’s intellectual property chapter, or the final TRIPS Agreement although they were “without a doubt a subject of discussion” (interview with a Canadian official, December 5, 2015). They reflected Canada-specific policy mitigations and clear concessions to the generic industry. In fact, stockpiling actually *violated* the TRIPS Agreement and the provision was successfully challenged at the World Trade Organization. In February 1999, the European Communities launched a WTO dispute under TRIPS Articles 27 (non-discrimination), 28 (patent owner rights), and 30 (exceptions to patent owner rights). A dispute panel was struck and ruled in March 2000 that the stockpiling provision in Canada’s *Patent Act* violated TRIPS Article 28.1 and could not be saved under the exemptions in Article 30. As summarized by the WTO:

Canada practically conceded that the stockpiling provision violated Art. 28.1, which sets out exclusive rights granted to patent owners... Concerning Canada's defence under Art. 30, the Panel found that the measure was not justified under Art. 30 because there were no limitations on the quantity of production for stockpiling which resulted in a substantial curtailment of extended market exclusivity, and, thus, was not “limited” as required by Art. 30. Accordingly, the Panel concluded that the stockpiling provision was inconsistent with Art. 28.1 as it constituted a “substantial curtailment of the exclusionary rights” granted to patent holders.¹¹⁹

¹¹⁹ WTO, (2015) “Canada- Pharmaceutical Patents DS114,” accessed November 5, 2015, https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds114sum_e.pdf; See also Report of the WTO panel: WTO, (2000) “Canada – Patent Protection of Pharmaceutical Products.” WT/DS114/R, March 17, 2000, accessed November 5, 2015, https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf

Had Canada implemented this provision differently, namely, with specific limitations on the allowable quantities, stockpiling might have been justifiable on the basis that it did not constitute “substantial curtailment” of the patent owner’s rights. But such a specific delineation would be very difficult to word appropriately (i.e. what would a stockpiling threshold be?) given that it would apply not only to pharmaceuticals but to all patented technology sectors. Under NAFTA (1709(7)) and TRIPS (27.1) patent rights must be enjoyable “without discrimination as to the field of technology.”

Furthermore, any thresholds would likely undermine the original purpose of the stockpiling provision, namely, for generic companies to accumulate enough product volume to quickly and decisively flood the market on patent expiry or a successful patent challenge. Following the WTO ruling, Canada removed the stockpiling exemption from the *Patent Act* in Bill S-17 2001, at the same time as it redressed the parallel challenge from the US regarding Canada’s phasing in of the 20-year patent term (Smith 2001). The early working provision was found to be TRIPS compliant and thus enables generic manufactures to rapidly market following patent expiry. However, the immediacy of high market penetration is somewhat less than it would have been had the stockpiling provision also been deemed TRIPS compliant.

PMPRB in Bill C-91

A significant portion of Bill C-91 1993 was dedicated to modernizing the Patented Medicine Prices Review Board. The legislation provided the Board with significant new powers that would help to offset the new IP rights provided under NAFTA and the draft TRIPS. Notably these included the power (per Section 81(2)(c)) to issue an order for the payment to the Federal Government (Her Majesty in right of Canada), to offset an

amount of “excess revenues estimated by the board to have been derived by the patentee from the sale of the medicine at an excessive price” (Bill C-91 1993, Section 81(2)). In keeping with the historical legacy of Bill C-22 1987, the determination of an excessive price (and thus excessive revenues) was significantly subject to the Board’s “opinion” (Ibid).¹²⁰ This considerable discretion continued to be manifest in the Board’s Excessive Price Guidelines.

The Guidelines would continue to be non-binding on the Board as a matter of law (s. 96(4)) and were exempt from the constraints of the *Statutory Instruments Act* which sets normal rules around Canadian statutes, regulations, and required consultations. In establishing the Guidelines, the Board was however mandated to consult with the Minister of Health, provincial Ministers of Health, representatives of consumer groups and the pharmaceutical industry (s. 96(5)). Bill C-91 built on the PMPRB’s flexibility and power. The Board would now be empowered to order financial penalties of up to two-times the amount of excess revenues accumulated when it deemed, based on the “extent and duration” of excess sales, that this was a matter of patentee policy.¹²¹ When implementing the legislation, the government affirmed that the strengthened PMPRB role related to consumer protection regarding patented medicines:

With Bill C-91, we also wanted to strengthen consumer protection, so that consumers can continue to obtain patented medicine at reasonable prices...the bill increases the power of the [PMPRB]. These new

¹²⁰ “Where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that, in the Board’s opinion, was excessive, the Board may, by order, direct the patentee to...pay...an amount specified in the order” (Bill C-91 1993, Canada Gazette III, Vol 16 (1), May 10, 1993: s. 83(2)).

¹²¹ “Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee...has engaged in a policy of selling the medicine at an excessive price, the Board may...direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will, in the Board’s option, offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee ...from the sale of the medicine at an excessive price” (Bill C-91, Canada Gazette III, Vol 16 (1), May 10, 1993: s. 84(4)).

powers will enable the board to more effectively control the prices of both existing and new medicines. The bill provides for fines and prison terms for those who do not comply with the board's orders...The board will thus be able to provide all Canadian consumers with even more effective price control. These new powers will authorize the board to order a reduction of prices it considers too high. It will also be able to impose fines of up to \$100,000 a day to compensate for previous overpricing and to discourage such practices.¹²²

In other words, the government wanted to leverage the existing institution to further constrain the full impact of patent protections as well as bolster penalties and incentives for compliance.

Board orders for price reductions and payments to the Crown were to be effective within one month (s. 84(1-2)) or as otherwise ordered by the Board and were considered a debt enforceable in the Canadian court system (s. 84(3)) where a Board order was “enforceable in the same manner as an order of the court” (99(1)). Board orders could simply be filed with the (Federal) Court to become an order of that Court (s. 99(2)). C-91 contained a clause implying, but not strictly mandating, that excess revenues reclaimed by the Federal Government could be redistributed to provincial governments (s. 103). The PMPRB has prominently framed the new power to order the payment of excessive revenues as being necessary “[i]n order to fill the vacuum created by the abolition of compulsory licenses” and “thereby further protecting the interests of consumers” (PMPRB 2015a, A1.3). These were substantial new powers that further helped to protect consumers from potential excessive prices under a patent monopoly.

Notwithstanding international trade agreements and pressure from the US, a large part of the *public* justification for increased patent protections under Bills C-22 and C-91

¹²² Pierre Blais, Minister of Consumer and Corporate Affairs, House of Commons Debate on Bill C-91, third reading, December 10, 1992, 14998-15001, accessed October 15, 2016, http://parl.canadiana.ca/view/oop.debates_HOC3403_12/196?r=0&s=1

was to increase research and development in Canada. To help secure Bill C-91, the industry, via its association the Pharmaceutical Manufacturers Association of Canada (PMAC), reiterated its commitment to invest 10% of sales in R&D. Per a June 1993 letter to Minister of Industry Michael Wilson, this PMAC commitment remained non-binding and heavily qualified by conditions related to the consistency of the business and regulatory environment:

Now that Bill C-91 has passed I would like to take this opportunity to discuss the investments our members expect to achieve. The achievement of these investments assumes that the international and national business and regulatory environments (including but not limited to such elements as patent protection, federal and provincial pricing regulations, approval of products for safety and efficacy and access to provincial formularies) for the pharmaceutical industry will not undergo substantial change...Association members stand by the Bill C-22 commitment to invest 10% of sales revenues in R&D by the year 1996 and to extend that commitment for as long as Bill C-91 stays in effect.¹²³

The earlier Bill C-22 commitment set an important path of voluntary and non-binding commitments that was maintained during 1993 reforms. The industry also made \$650 million in advance investment commitments that the government was able to leverage in helping to make the case for C-91.¹²⁴ This was part of a massive public relations effort that the government undertook in the face of considerable criticism of the bill.

Figure 3.2 compiles key insights from a comprehensive qualitative analysis of over 200 mostly unpublished speeches delivered by Michael Wilson, Minister of Industry, Science and Technology, and Minister for International Trade between April

¹²³ Letter from Judith A. Erola, President of PMAC to Hon. Michael Wilson Minister, Industry, Science and Technology, June 10, 1993, as published by the Government of Canada: Government of Canada, "Review of the Patent Act Amendment Act, 1992 (Bill C-91): Information" February 1997 Industry Canada, Distribution Services, Ottawa ON.

¹²⁴ Notes for Michael Wilson Speech on Bill C-91 to "Senate committee," January 21, 1993.

1991 and June 1993.¹²⁵ Many of the quotes illustrate the cumulative nature of trade agreements and that market power, while important, is not the only factor that explains the NAFTA IP outcome. For example, the legacy of Bill C-22 and the existence of a successful pricing regulator was key to securing support in Canada.

In summary, as trade-related intellectual property protections expanded, Canadian consumer protection institutions evolved to build their capacity as a counter weight. Institutions developed new safeguards with new financial teeth, to prevent the abuse of patent monopoly power. As shown in the next section, protection of these institutions substantively shaped the establishment of the international IP regulatory regime.

Figure 3.2: Excerpts from Minister Michael Wilson Speeches 1991-1993

Speaking Engagement	Quote	Significance
Arthur Andersen Symposium St. Charles II, June 2, 1992	“The GATT was the foundation upon which the Canada-U.S. Free Trade Agreement (the FTA) was built. Equally it is the basis for negotiation of other trading arrangements, such as the proposed [NAFTA]. Furthermore, the GATT will provide the basis for expanding continental trade with the emerging European Community and the high-growth Asia-Pacific region.”	Shows how policy makers view trade agreements as cumulative. New standards build on previous standards.
Notes for an address at the conclusion of the North American Free Trade Agreement August 12, 1992	“Canada has benefited from the dispute settlement process established in the FTA. We have won a majority of cases. And now we have negotiated a strengthened dispute settlement system with safeguards to ensure that the system runs fairly. The rule of law, not power, will prevail in settling disputes.” “The NAFTA itself need not be a closed club. Perhaps, too, this deal will lend some impetus to the worldwide trade negotiations in the GATT, where Canada has been playing a leading role”	Shows how rules-based trading and dispute resolution institutions are explicitly intended to mitigate power factors. NAFTA was designed for expansion.

¹²⁵ Library and Archives Canada maintains the original Minister’s Orator documents which are typically typed or faxed with frequent hand written notes between Minister Wilson and his staff. These speeches duplicate many of the same key messages. Frequently these notes are candid and humorous: “J.F.: This is a badly written. We MUST talk about these speeches. We have got to do better. Who is writing them. Are we paying them?!... This is a terribly written page. High School!” “Whoever wrote this is not thinking in today’s terms. – See my changes and reflect in future.” A more detailed version of this table providing additional interesting context is provided in the ANNEX.

Speaking Engagement	Quote	Significance
Wall Street Journal Conference, New York, September 24, 1992	“Rather than hindering the multilateral process, the NAFTA should provide an impetus to the successful conclusion of the Uruguay Round... It will ... show other newly industrialized and developing countries that they, like Mexico, can successfully enter into freer trading relationships with developed countries. This is very important to us.”	Illustrates the view of NAFTA as a pump-primer.
Talking points Faxed to Minister November 25, 1992 in response to Canadian Press wire by Dennis Bueckert on opposition to Bill C-91.	Talking Point: “[C-91] is good for Canada: more investment (\$500 M plus); more high skilled jobs; more research; better medicines; strong price control; reward for innovation... Canada has been holding its own, <u>but</u> , if we want investment we must act now, [Canada is] at a critical juncture...Note [the] track record of C-22:[drug] prices [increasing] below [the] consumer price index]; investment up; jobs up.” Minister Wilson additional hand written notes: “[Canadians] say they want R&D, [Investment], high tech jobs...But you can’t just wish this...C-91 will help... Delaying treaties risks [investment]; Should concentrate on price control regime”	Shows responsible Minister’s thinking and that price control regime was central to legitimizing increased patent protection; illustrates how the legacy of previous institutions under C-22 1987 was key to the argument for C-91 1993.
Notes for an address by Michael Wilson, Third Reading of Bill C-91 December 10, 1992.	“opponents [of Bill C-91] say that drug prices will soar as a result of Bill C-91. They won’t. They haven’t in the past and they won’t in the future. The [Patented Medicines Prices Review] Board has been given new power over both new and existing patented drugs. These powers include the ability to roll back prices, recover excessive revenues, impose fines and imprison offenders. This Bill has teeth – sharp teeth.”	Shows how the record of drug pricing under the FTA-era institution was used to justify further IP protections and a strengthened PMPRB.
Third Reading Debate on Bill C-115, The NAFTA Implementation Act, Ottawa ON, May 27, 1993	“Canadian Businesses gain new intellectual property protection in the NAFTA...As the Canadian Economy moves into higher value-added, knowledge-based growth areas, this protection...will protect our ability to expand into the NAFTA area”	Shows an important link and trade-off on intellectual property. Enhanced IP protection would facilitate Canada’s access and expansion into the NAFTA area market.

Canadian Institutions Shape International Regulatory Outcomes

Canada’s existing price control regime was also a major subject of discussion in the TRIPS context. According to Canadian officials, a key subject of discussion under TRIPS was the so-called “nullification or impairment” provision in GATT Art. XXIII. Among other causes of action, these provided GATT signatories with “non-violation complaint” remedies where they alleged another signatory was nullifying or impairing an objective

of the agreement.¹²⁶ Protecting Canada's right to regulate was an import point of discussion:

[The PMPRB was discussed] less so in NAFTA, but a hell of a lot more so in the context of the TRIPS Agreement... Because, certainly, Canada was not willing to take on any obligations that would affect the ability of how you price pharmaceuticals, domestically, and the controls, and the price controls, in essence, which the Patented Medicine Prices Review Board is... And I don't recall this coming to a head in the NAFTA context, but by that time we had kind of fought to a draw in the...WTO...[a key issue was] the nullification [or] impairment provisions of the GATT... there were lengthy debates as to whether the nullification [or] impairment provisions of the GATT would apply to TRIPS. And ultimately the saw-off we reached, which was in fact subsequent to NAFTA, but nevertheless, the final version of the TRIPS Agreement was that it wouldn't apply, but it would be reviewed every five years. We included it in the text as applying, and then, in essence, negated that inclusion for five years to be reviewed every five years, and since then every five years they've continued to apply that waiver, so, nullification [or] impairment hasn't applied...One of the issues that was foremost in the Canadian context was, would the pricing of pharmaceuticals be deemed to be a nullification of rights, even though it wouldn't be an actual violation of the agreement... and that's why [Canada] fought pretty hard to insure that that wasn't going to be the case. Now the Americans always claimed, 'no, no, there couldn't possibly be a nullification [or] impairment in a non-violation case based on pricing' but [Canada wasn't] convinced of that (Interview with a Canadian official, December 5, 2015).

This refers to Article 64.2 and 64.3 of the TRIPS Agreement that excludes non-violation and "situation complaints" for the first five years of the WTO and required the TRIPS Council to submit recommendations on continuance of the moratorium for "ministerial

¹²⁶ Article XXIII:1 of GATT 1994 provides three scenarios for a nullification or impairment or impediment of attaining any objective of the agreement: "a) the failure of another contracting party to carry out its obligations under this Agreement, b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or c) the existence of any other situation." Pursuant to Article XXIII:1(b) of GATT 1994, provision (b) could lead to a non-violation complaint: "A non-violation complaint may be used to challenge any measure applied by another Member, even if it does not conflict with GATT 1994, provided that it results in "nullification or impairment of a benefit". WTO, "Types of complaints and required allegations in GATT 1994" Article XXIII:1 of GATT 1994, accessed December 10, 2015, https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c4s2p1_e.htm

consensus.”¹²⁷ It is clear that the preservation of Canadian pricing institutions was a major factor in the negotiated outcome on TRIPS. With this issue of nullification or impairment being negotiated in the TRIPS context, Canada was confident to affirm the role of the PMPRB as “hereby continued” (Bill C-91, s. 91(1)) and was thus provided considerable latitude to further shape its function under domestic law and regulation. In fact, NAFTA negotiations did not substantively cover specifics of the Board itself, but Canada was careful to preserve the ability of its institutions to function appropriately. As recalled by one Canadian official “the actual review Board, as such, was never the subject of negotiations, [however] the issue of whether pricing [regulation] of pharmaceuticals could or could not happen was very much at the forefront of all [of Canada’s] thinking” (Ibid).

Canada’s attainment of limits to non-violation actions to protect its price regulation institution provides context to the idea that international regulatory outcomes can be significantly shaped by existing domestic institutions. The *expanded* powers for the PMPRB and other elements of Bill C-91 show that implementation of an international standard can contain many other features not feasibly covered in broader multi-party negotiations. Particularly in the regulatory context there is a clear domestic institutional and historical bias that shapes negotiating perspectives:

Now-a-days, international trade policy is really the parallel to domestic economic policy... Everybody goes into any kind of international negotiation on the basis that ‘my system is best’...[and] particularly in the regulatory context, that’s ten-fold increased. Because every regulator thinks that ‘my regulations are ok, and everybody’s got it

¹²⁷ Despite some controversy among WTO members regarding the potential status of the moratorium in absence of TRIPS review and ministerial consensus, no TRIPS non-violation or situation complaints have been brought forward as of 2015. WTO, “Types of disputes in the TRIPS Agreement,” accessed December 10, 2015, https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c4s5p1_e.htm

wrong' ... and interestingly, the countries that tend to do best in these kind of negotiations are the ones that manage to bridge the gap between the... trade negotiators and the domestic regulators and come up with positions that resolve both their interests (Interview with a Canadian official, December 5, 2015).

This local regulatory bias and institutionalized negotiation strategy must be better factored into scholarly accounts of international regulatory regimes and their determinants through historical institutionalism. From this account it would seem that those countries that have existing internal bureaucratic linkages between regulators and trade officials would have some advantages in securing their own domestic rules as part of the international standard. If such internal state linkages can be considered a function of negotiation *capacity*, this practitioner insight would seem consistent with other HI work on regulatory standard setting that attributes significant importance to the sequencing of institutional capacity (Bach and Newman 2010).

One of the key manifestations of this phenomenon in the TRIPS context was the definition of patentable subject matter with respect to microorganisms. Due to high politicization and international impasse between the US and the rest of the world, TRIPS effectively adopted Canada's standard regarding the patentability of microorganisms:

the history of patentability of life forms...was the Americans desperately having to prove the patentability of the Harvard Mouse; wanted *that* to be the standard...Nobody else in the world wanted...it to go that far, except the Americans, and that included [Canada] and the Europeans and of course a whole range of developing countries. There was massive lobbying done, particularly by the agricultural lobbies, in that regard...and ultimately...we came up with a Canadian solution. Because we had a lengthy theological debate that we were never going to get out of. And the question that [Canada] asked ourselves...and subsequently asked everyone else is, well, what the hell do we do *now*? And well it turned out that the practice in most countries was that we *did* patent microorganisms... we took what in essence was the practice in Canada, and that was acceptable to everybody, ultimately. And that

is what became the TRIPS text...(Interview with a Canadian official, December 5, 2015).

This reflection provides some clues as to how historical and power factors can combine to produce international regulatory outcomes. Where American market power and intense lobbying by a powerful business sector was not a sufficient condition to produce an outcome, regulatory history and the ability to leverage an existing standard was determinative to Canada's advantage. It leveraged the existing institutional framework in Canada and elsewhere to design and entrench those local standards in an international treaty. In other words, the path dependence of historical policy, and not strictly US market power, set the standard.

Regulatory institutions are sticky in the sense that once a standard is set there seems to be a natural inclination to see reinforcing policy feedbacks. This can greatly complicate the process of standard harmonization and regulatory cooperation. When there is conflict between established standards, it is difficult to predict which standard will be adopted, for example, when an international standard is proposed by a large market power but a smaller power has a history with something different. Both the international standard and the local standard will have its own associated path-dependence "impulse" or "force"—for lack of a better term. Market power is one potential predictive explanation for which institutional legacy will be more powerful and set the standard. Another potential explanation is functionality or which standard does the best at achieving its goal. A related but distinct concept to functionality is legitimacy where social norms may be a determinant. Another still is temporal proximity where an older entrenched standard may face the lowest barriers to adoption. The historical institutionalist notion that the longer a standard is in effect the more entrenched and

resilient it will be is intuitive, particularly when considering macro-social institutions such as property rights, or even intellectual property rights. This would seem less applicable to individual rules and regulations that may be more fungible. And in new areas of regulation there may be completely different predictive principles, for example, a first-mover advantage where the first to regulate is the party to set the standard.

This concept of a first-to-market advantage is also intuitive.¹²⁸ We can predict first-movers will have an advantage in new areas of regulation. Cooperation may also be easier when working jointly from the outset or early stages of a technology or new regulatory area. The cooperative challenge for policy makers—and the predictive challenge for scholars—comes when divergent regulations are already established. Even for power asymmetries as stark as Canada-US relations, insights arising from a market power hypothesis are not always predictive. Nor does historical institutionalism as a backwards-looking framework have much to offer from a predictive perspective. Perhaps the only *predictive* insight that can be taken from this chapter is that local regulatory institutions will impart a local regulatory bias and new regulatory systems will significantly reflect past policy choices.

¹²⁸ In the context of bilateral regulatory harmonization, former US Ambassador to Canada Bruce Heyman has made apt comments regarding the temporal challenges associated with international regulatory cooperation: “there are existing regulations, and there are new regulations... existing regulations where there are [international] differences, those are the hardest to actually deal with because everybody digs their heels in a bit in terms of believing their way is the right way. But in new regulations, no standards have actually been set yet. And it gives you an opportunity... to create jointly the set of regulations. That happens more easily where we’re doing something together and we’re actually creating something at the same time... Where it’s a bit more challenging is a regulation is set on something that is not yet in the other country. And so you end up finding a new innovation, or creation... that the country in which its starting in, ends up regulating” Ambassador Bruce Heyman, Remarks, June 9, 2016, Ottawa, Canadian International Council.

Conclusion

This empirical work provides support for the hypothesis that local institutions matter even when at odds with considerable power dynamics. Price control institutions initiated under the Canada-US FTA provided a base for elaboration under NAFTA and TRIPS implementation. Canadian officials preserved space for price regulations with a renewable exemption from nullification or impairment provisions thus significantly shaping the international standard. Where US power failed to establish definitions of patentable subject matter, Canada's pre-existing path provided the model and set the international TRIPS standard.

This helps to illustrate several interesting aspects of institutions and sequencing. When market power is insufficient to produce an outcome, a pump-primer or legitimation strategy may help to produce a regulatory outcome. This was true both for the novel insertion of intellectual property provisions within a trade agreement as well providing impetus to finalize a broader multilateral treaty. When setting specific standards within a negotiation, small powers can have asymmetric influence by recognizing temporal opportunities and by leveraging and protecting existing domestic standards. Given the interrelationship between trade and economic regulation, it also seems helpful to have well-established working relationships at the domestic level between trade officials and regulators.

This chapter supports the notion that trade agreements and regulatory standards cumulate and build off of past standards. International regulatory regimes and the domestic regulations they produce are clearly impacted by historical policy choices. Historical institutionalism can help illuminate valuable nuance undergirding more

obvious power relationships. The following chapter picks up this argument and chronology by examining the next phase of NAFTA and TRIPS regulatory implementation.

Chapter 4 - Regulatory Feedbacks Part 2: Regulatory Implementation and Evolution

This chapter argues that domestic institutions and interests powerfully shape the implementation of international standards. Market power is less significant in this regulatory implementation context. The chapter continues the analysis and chronology of NAFTA and TRIPS implementation with a particular emphasis on patent dispute mechanism regulations. A central feature of Canada's adoption of US-style intellectual property (IP) protections was to link the marketing approval of a generic drug to the patent of its corresponding brand drug. This is commonly called "patent linkage." Patent linkage was implemented in 1993 via the *Patented Medicines (Notice of Compliance) Regulations (PM(NOC))*. The regulation was designed to offer an effective injunction period under intellectual property (IP) litigation but was implemented in a way that diverged considerably from those US standards it was based on.

Market power theory would predict that standard-taker nations simply adopt the standard-maker's regulatory approach. Evidence of a full policy diffusion of US standards would support a market power approach. Evidence of a partial policy diffusion heavily influenced by entrenched domestic interests would tend to support an historical institutional approach. A powerful standard-maker should be able to completely translate its standards and ensure that they are binding within a treaty. Evidence that the standard-taker can keep key regulatory elements out of the treaty and implement international standards according to its domestic interests would be a smoking gun that market power does not fully explain regulatory outcomes. Indeed, some points of international

negotiation are not even codified in trade treaty text but are *related concessions* where a country agrees to alter domestic economic regulations. As such, these policies are subject to future domestic refinement and elaboration. From a theoretical perspective, the discussion of patent linkage is important because it shows how trade negotiations are inseparable from domestic economic regulation. A key standard-maker objective of negotiations is to alter domestic economic regulatory policy of the standard-taker. This objective is never fully realized because standard-taker nations retain institutional sovereignty and international policy translation is often incomplete.

Best practices for process tracing suggests that we should be equally tough examining alternative explanations and combine process tracing with case comparisons when useful for the research goal (Bennett and Checkel 2015b, 260). As the most US-style IP protection modeled after US policy, patent linkage could easily be raised in the context of the alternative market power hypothesis. For example, one could argue that under patent linkage, Canada simply bowed to US market pressure and adopted its favoured standard “in exchange for preferential trade terms” (Bouchard et al 2011, 5). In other words, patent linkage requires examination because it presents a *most* critical-case *policy* within the critical-case of Canada. However, even here we find considerable domestic institutional resilience and resistance. The path forged by the US system of patent linkage was only partially exported to Canada. It clashed with a domestic path, legal institutions and an institutionalized interest coalition.

First, the chapter discusses patent linkage in greater detail. These standards did not go nearly as far as the US standards they were modeled on. It leverages a within-case comparison of the *PM(NOC) Regulations* related to patent disputes and the *Patented*

Medicine Regulations related to the PMPRB pricing regulation discussed in the previous chapter. It shows that patent linkage regulations, which expand IP protections, were implemented carefully to narrow and limit the full impact of those new patentee benefits.¹²⁹ The chapter then considers NAFTA implementation and argues that the politics and sequencing of treaty implementation matter. If power asymmetry fully explained the NAFTA outcome then the sequencing of implementation should not matter. However, this was a factor in Canada's case. Finally, the chapter considers a statutory review of NAFTA-era intellectual property reforms and the evolution of patent linkage in contemporary debates. It argues that Canada preserved domestic sovereignty by retaining flexibility to limit and reduce IP protections in the future. A powerful institutionalized interest coalition continues to shape these IP policies on an ongoing basis. In 2017, Canada's patent linkage policy is slated to be replaced following significant domestic stakeholder lobbying, and much to the chagrin of the US industry. If only US market power mattered, Canada would not have been able to maintain its flexibility to unilaterally reform patent linkage in support of its domestic industry.

Patent Linkage: A New Patent Adjudication Process and Injunction Period Under The Patented Medicines (Notice of Compliance) Regulation 1993

This section traces the implementation of patent linkage. It compares this IP-expanding regulation (patent linkage) to the IP-restricting regulations (the Patented Medicines Prices Review Board) discussed in earlier chapters. It argues that the details of regulatory

¹²⁹By comparison, the PMPRB and its *Patented Medicines Regulation* is an inherent constraint to intellectual property protections. The PMPRB has broad jurisdiction and its scope and role was strengthened in the NAFTA-implementation context. This jurisdictional comparison illustrates important nuances within these distinct but complementary regulations and their treatment within Canadian courts.

implementation mattered for Canada's IP regime. The policy imparted important local nuances that distinguished it from the parallel US policy.¹³⁰

Patented Medicines (Notice of Compliance) Regulations (PM(NOC)) are a distinctly Canadian regulatory alternative to “interlocutory injunction” in patent litigation. Interlocutory injunctions are temporary interventions by the court that prevent parties from engaging in certain activities such as marketing a product while a matter is being litigated. Injunctions are particularly important for patent *holders* in the event of a patent dispute because they can prevent a competitor from entering the market and eroding market share during the lengthy litigation process. Canadian courts historically had high standards for interlocutory injunction and thus did not have an *effective*, routine mechanism for injunction in pharmaceutical patent litigation. A new mechanism modeled after the US system was created under the *PM(NOC) Regulations*. In simple terms, this policy created a separate stream of litigation for pharmaceutical patent disputes where the marketing approval¹³¹ of a generic drug was linked to the patent status of its corresponding brand product (Lexchin 2011). The process provided temporary relief from competition during a streamlined judicial review process. This initially offered a 30-month period of protection but was subsequently limited to 24 months following a review by Parliament. This was possible due to an inherent flexibility for future amendment combined with a strong stakeholder coalition response.

¹³⁰ As illustrated below, these local nuances included: 1) a summary adjudication mechanisms rather than a full patent infringement hearing; 2) no appeal rights for patentees in this summary process; 3) no patent term restoration for regulatory approval time as found in the US *Hatch-Waxman Act*; 4) special damages provisions with considerable potential penalties for patentees; and 5) other jurisdictional and application nuances and practical impacts created subsequently in case law such as a “reverse onus” (as summarized in Figure 4.1 below).

¹³¹ Health and safety regulatory approval is administered by Health Canada, which is the equivalent body to the Federal US Food and Drug Administration (FDA).

Canada's patent linkage regime continues to govern how pharmaceutical patents are protected and disputed. It became a major subject of Canada's subsequent international trade negotiations such as the Canada-EU Comprehensive Economic and Trade Agreement (CETA). The regime was loosely modeled on the US-style system established under the *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)*. This US legislation also provided a 30-month stay for patent litigation. The US law was generally more favorable to patent owners because Canada's linkage adjudication provided them with no rights of appeal. Additionally, Canada's system diverged significantly from the *US Hatch-Waxman Act* in that it did not offer a compensatory period of protection for the time that products undergo regulatory approval. This is typically referred to as 'patent term restoration' or supplementary protection certificates in Europe (Hore 2000).

Neither the TRIPS nor NAFTA text specifically states that the marketing approval of a generic drug needs to be "linked" to a brand product's patent status. Indeed not all countries have a system that does so. However, to comply with the patent rights conferred in TRIPS Article 28, and its corresponding Article 1709 (5) of NAFTA, signatories must offer *effective* protection. Per TRIPS, signatories must prevent third parties from "making, using, offering for sale, selling or import" (TRIPS 1994). Per NAFTA, signatories must prevent "other persons from making using or selling the subject matter of the patent" (NAFTA 1993). As such, countries must extend effective protection throughout patent litigation.

The appropriateness of Canada's pre-Bill C-91 regime for injunctive relief in pharmaceutical patent disputes has been an ongoing point of concern and debate.¹³² Legal practitioners in Canada will be aware of the high judicial standards of “irreparable harm” for normal injunctions. According to one legal practitioner “interim injunctions are rarely, if ever, granted in patent infringement cases before the Federal Court of Canada and...a high threshold of irreparable harm must be met by the party requesting such an injunction” (Steele 2003, 4). In the absence of introducing routine recourse to patent infringement injunctions via legislation, a new measure was required in Canada's case so as to conform to international trade agreement requirements regarding “*effective protection*.” Despite the lack of reference to patent linkage in treaty text, Canadian and Mexican patent linkage provisions clearly arise from trade commitments. As noted by Canadian Prime Minister Brian Mulroney, his government's enactment of the *PM(NOC) Regulations* was a key part of the NAFTA implementation process:

In order to harmonize the protection for innovation offered by its principal trading partners...Under both NAFTA and TRIPS, Canada agreed to provide expeditious and effective remedies to prevent the infringement of intellectual property rights and recognize the value of the confidential data submitted by innovative pharmaceutical companies seeking approvals for new drugs. As such, the Patented Medicines (Notice of Compliance) Regulations came into force in March of 1993 (Mulroney 2012).

The idea of protecting clinical trial data from being used for a generic manufacturer's market approval for a period of five years is one aspect of this commitment (5 years of

¹³² For example, see the testimony of John Manley, Minister of Industry before the Standing Committee on Industry during its retrospective review of Bill C-91 and the *PM(NOC) Regulations*. Manley highlighted the issue of effective injunction: “There is no doubt that you will want to look at the fairness of these regulations. [Is it] true, as some claim, that traditional injunctive relief in Canada is not sufficient to address pharmaceutical patent infringement?” Hon John Manley, Testimony Before the Standing Committee on Industry, Monday, February 17, 1997, accessed June 11, 2016 http://www.parl.gc.ca/content/hoc/archives/committee/352/indu/evidence/42_97-02-17/indu42_blk-e.html

data protection is found in NAFTA only). Another is preventing generic marketing approval based on a patented product's submitted clinical data until the courts have adjudicated disputes on that patent. For practical purposes, harmonization with "trading partners" can be considered shorthand for harmonization with Canada's most important trading partner, the United States. The US pharmaceutical industry and its subsidiaries in Canada pushed strongly for patent linkage.

Canada adopted a modified *Hatch-Waxman-style* system of patent linkage (Faunce and Lexchin 2007). General alignment with the US was a practical, yet somewhat contentious, alternative to overriding years of Canadian case law on interlocutory injunctions via legislation. It was contentious partly due to the obvious barriers it would create for the market entry of generic drugs. Equally, linkage was controversial due to the US policy it was modeled after. For example, the US *Hatch-Waxman Act* was viewed as incentivising so-called patent "evergreening." Evergreening is a general term applied to various patenting strategies that attempt to prolong the effective patent life of a compound. *Hatch-Waxman* did not prevent multiple automatic injunction periods for the same product (Ibid, 2). This loophole was later closed in both the US and Canada.¹³³

The provision of regulations on patent linkage were outlined in Section 55.2(4)(a-e) of Bill C-91. The section empowered the Governor in Council to make regulations regarding the timing of market approval for persons other than a patentee (i.e. a

¹³³ In 2003 Congress limited automatic injunctions under the *Hatch-Waxman Act* to one per product. Similarly in 2006, Canada amended the PM(NOC) Regulations in part to add safeguards against multiple patenting through a patent list "frozen" as of the date of a generic company's market approval submission. Health Canada (2015) *Guidance Document: Patented Medicines (Notice of Compliance) Regulations*, 15-101151-734, accessed December 2, 2015, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.pdf.

subsequent generic producer). This included the power to set the conditions and earliest day of marketing approval of a generic drug, the dispute resolution mechanism, remedies available to the competent court, and general provisions governing the regulatory market approval of generics that could potentially infringe a patent.¹³⁴

This power was implemented through the *PM(NOC) Regulations* on March 12, 1993, just over a month after C-91 was assented to (Canada Gazette Part II Vol. 127, No. 6, SOR/93-133). The *PM(NOC) Regulations* created a patent registry to be maintained by the health products regulator, the Minister of National Health and Welfare (now the Minister of Health) (3(1)).¹³⁵ This would be separate from the full national patent registry maintained by the Canadian Intellectual Property Office (CIPO). Producers of patented medicines could file their patents and associated expiry dates with the Minister who would include them on the Health Canada patent list (s. 4(2)). Generic producers would not be granted marketing approval (a notice of compliance or NOC) if its reference brand comparator was listed on the patent registry. On application for an NOC, the generic

¹³⁴ Under Section 55.2(4) the Governor in Council was empowered to make regulations: (a) “respecting the conditions that must be fulfilled before a notice, certificate, permit, or other document concerning any product to which a patent might relate...;” (b) “respecting the earliest date on which a notice, certificate, permit or other document.. that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;” (c) “governing the resolution of disputes between a patentee... and any person who applies for a notice, certificate, permit or other document... as to the date on which [it] may be issued or take effect;” (d) “conferring rights of action in any court of competent jurisdiction with respect to any disputes... and respecting the remedies that may be sought in the court, the procedure of the court in the matter and the decisions and orders it may make;” (e) “generally governing the issue of a notice, certificate, permit or other document ... in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent” (Bill C-91 1993).

¹³⁵ The Patent Register for medicines is maintained by Health Canada and is provided in searchable form by medicinal ingredient, brand name, strength and dosage form, drug identification number (DIN) patent number and expiration date. Health Canada, Patent Register, accessed December 12, 2015, <http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp>

producer would be required to state they accept “that the notice of compliance will not issue until the patent expires; or allege that...the patent is not valid” (s. 5(1)).¹³⁶

In the event of a Notice of Allegation, the generic company would be responsible for providing “a detailed statement of the legal and factual basis for the allegation” (per 3a) and serving notice to the patent holder (per s. 3b). Following this notice, the patentee would then have 45 days to apply to the court for “an order prohibiting the Minister from issuing a notice of compliance” until patent expiration (per s. 6(1)). The Minister would be prohibited from issuing a notice of compliance to the generic producer for 30 months following confirmation of patent owner’s application to the court. This prohibition would terminate on patent expiry (per s. 7(2a)), withdraw of the application or termination by the court (per s. 7(4)), or if the court “declared that the patent is not valid or that no claim for the medicine itself and no claim for the use of the medicine would be infringed” (per s. 7(2b)). The court was empowered to shorten or lengthen this period of time under some circumstances such as unreasonable delays of the proceeding (per s. 7(5)).

The generic industry was able to secure some important trade-offs in relation to these patentee protections. Section 8 of the regulations dealt with patentee liabilities for any time a generic was unjustly blocked from the market. It provided relief to generic manufacturers through court ordered damages. In practice, an assessment of so-termed “Section 8 damages” would have to identify a time period and construct a scenario over which hypothetical generic company profits would be assessed. In essence, the government punted the details of this section to be determined by the courts. This deferral

¹³⁶ This is called a “Notice of Allegation.” The basis for a Notice of Allegation are: a patentee’s statement of ownership is false (per s. 5(1)b i); the patent “has expired” (per s. 5(1)b ii); the patent is “not valid” (per s. 5(1)b iii); or “no claim for the medicine itself and no claim for the use of the medicine would be infringed” by the application (per s. 5(1)b iv).

would shape the ultimate extent of the damages provisions. The lack of regulatory direction on the calculation of Section 8 damages has led to considerable confusion and some questionable case law. For example, patentees risk penalization when unsuccessfully protecting patents in PM(NOC) litigation. One IP practitioner explains how the court has created the potential for generic company windfalls:

The damages under [the Section 8] provision have been likened to damages owed if an interlocutory injunction is granted but the case is not proven. However, a "hypothetical world" must be created by the Court to try to recreate the scenario that would have occurred [sic]... As a result of the legal uncertainty surrounding the conditions of this hypothetical world, recent Court decisions have resulted in a windfall to generic companies when these damages are calculated in the face of multiple NOC Proceedings against multiple different generic companies... the size of the generic market can be determined for each of them independently, and without any real-world knowledge of when each company actually entered the market after the conclusion of their respective NOC Proceedings... This is contrary to the purpose of damages, which are meant to compensate for loss, not provide a windfall (Moore 2015).

In other words, the uncertainty created by the regulation and a lack of specific conditions associated with the calculation of hypotheticals has impacted real-world financial outcomes for some patentees. This observation is interesting for several reasons. It appears that case law has greatly altered the penalties and incentive structure associated with litigation under the original *PM(NOC) Regulations*. The root cause appears to be an imprecise approach to trade commitment implementation and considerable deference to the courts. This has apparently amounted to substantial new costs for any drug patenting that might be overturned. Of course this will not stop companies from patenting or employing the linkage regulation to delay generic market approval. However, it does

create a new notional *penalty* (as opposed to simple compensation) not conceived of in the *Patent Act* as amended during TRIPS and NAFTA implementation.¹³⁷

Additionally, the courts have interpreted that the patent owner assumes a *de facto* burden of proof (on a balance of probabilities) that none of the allegations made by a generic producer are justified (Richardson et al. 2004). Despite generic company displeasure with the existence of linkage regulations, the issue of windfall damages and burden of proof both seem to be highly favourable to those litigants. Some legal practitioners have written on the questionable logic of the *de facto* reverse onus:

In any practical context, it is logical that the person making an allegation should bear the burden of proving its veracity. Notwithstanding logic, the PM(NOC) Regulations requires the first person [brand owner], in bringing the application, to effectively disprove each and every allegation made by the second person [generic producer] in the [Notice of Allegation]. It is especially bizarre in the context of an allegation of noninfringement where, the proof of the allegation rests in the hands of the second person (or its drug supplier). The problem is further exacerbated by the fact the Courts have held that allegations in a NoA are presumed to be true (Richardson et al. 2004).

These insights are of a high profile IP lawyer acting for patent-owning clients. In keeping with Bennett and Checkel (2015b), the normative elements of this commentary should be viewed under the lens of potential bias. However, there can be no doubt that the onus system is structured—and has evolved in case law—to be highly favourable to second entrant companies who seek market approval *before* a patent has expired.

A further feature of the system was its design as a summary adjudication mechanism to be used in advance of a generic market entry. It did not include the normal

¹³⁷ By contrast, the US system has 1) full patent hearings under an automatic 30-month injunction period, 2) full appeal rights for both litigants, and 3) a 180-day period before other generics can enter the market to compensate the first generic entrant for successfully challenging a patent. When a patentee wins, the brand company can claim up to triple damages in some cases (see discussion below).

features of a full trial including appeal rights. PM(NOC) proceedings can be appealed by a disappointed generic litigant. This opportunity is not afforded to a patent holder who has no rights of appeal under the PM(NOC) regulations. This is a major point of contention for the patent-holding industry. Patent holders will often launch a full infringement action while simultaneously defending themselves against the Section 8 damages following from a PM(NOC) decision (Tanner 2012). Additionally, those PM(NOC) decisions are effectively binding on the patent owner for future generic entrants. This is because re-litigating subsequent Notices of Allegation brought on the same basis is considered an abuse of process and thus subject to a summary dismissal application by the generic manufacturer under subsection 6(5) of the regulations (McCurley and Lucas, 119). As such, a failed PM(NOC) defense to an NOA effectively opens the market up to other generic applicants. Therefore, the stakes are quite high in these proceedings.

It should be reiterated that the *Patented Medicines Regulation* and *Patented Medicines (Notice of Compliance) Regulation* are distinct orders with different purposes. The Federal Court of Appeal in *ICN v. Canada (PMPRB) (1996)* reinforced that “the [respective] definitions of ‘medicine’ and the language referring to relevant patents are more expansive in the case of the excessive pricing provisions” (Critchley 2002, 13). This raises an interesting point of comparison that illustrates the self-constricting nature of the IP policy environment in Canada. Figure 4.1 below compares select features of each regulation with respect to jurisdictional issues and notional favourability to patent owners. For patent linkage—regulations notionally favourable to IP owners—policy scope is narrow and specific. High specificity requirements regarding eligibility for

patent linkage protections were made even more specific in case law. This narrowed the scope of the benefits to patentees. Narrow time constraints for application of the regulations apply without any opportunities or remedies after an initial 45-day application window. There are low costs and few barriers to generic manufacturers making a notice of allegation and high penalties for patentee loss in a patent linkage proceeding. As discussed, there are no appeal rights for patentees. Given this design, it is perhaps not surprising that the generic industry has been successful in more than 70% of patent linkage cases decided since 1993 according to generic industry association analysis.¹³⁸

Conversely, PMPRB price regulation is notionally *unfavourable* to patent owners. However, nearly every element of the PMPRB rules and jurisdiction provides it with expansive power. This power has grown in case law. Low specificity requirements for jurisdiction have been further entrenched by the courts. Time constraints regarding the Board's jurisdiction are retroactive to the patent pending period. Penalties associated with losing a hearing are substantial and have escalated since the PMPRB's inception.

The significance of these points and nuances as a matter of perspective should not be overstated. However, the comparison is made here to illustrate that IP-expanding policies (patent linkage) are implemented in the Canadian system with many constraints, safeguards, and considerable capacity to roll them back in the future. Conversely, IP-constraining policies (the PMPRB) are applied liberally so that institutions are significantly empowered and these powers could escalate over time. This may be entirely appropriate from a domestic sovereignty perspective but is a nuance lost in the rancour of the political debate on pharmaceutical IP in Canada.

¹³⁸ As of February 2012. Canadian Generic Pharmaceutical Industry, Letter to Simon Kennedy, Senior Associate Deputy Minister, Industry Canada, February 21, 2012, obtained under the *Access to Information Act*.

Figure 4.1: Comparison of Jurisdictional Issues Associated with *Patented Medicines (Notice of Compliance) Regulations* (Patent linkage) and the PMPRB

	Notional Favourability to Patent Owner	Jurisdiction	Time Constrains Regarding Application/ Jurisdiction	Jurisdiction Specificity Requirements	Treatment by the Court	Penalties Associated with Losing a Case
Patent linkage <i>PM(NOC) Regulations</i>	High: patent linkage is a key IP protection	Linkage only applies when patentee takes action	Narrow and time-limited: a 45 day application window for patent linkage after which no patentee recourse for linkage protection; “use it or lose it”	High criteria for inclusion on the protected patent list; ¹³⁹ onerous disclosure requirements and may even narrow eligibility for linkage; “Frozen” patent list added in 2003 further constraining patentee flexibility	Expands specificity requirements beyond Regulator Guidance documents (per <i>Gilead v. Canada</i> 2012; <i>Novartis v. Canada</i> 2012; <i>Purdue v. Canada</i> 2010) ¹⁴⁰	Low for generic (only legal costs); No barriers to challenge patent in advance of its expiry. High for patentee: legal costs plus Section 8 damages; see discussion of ‘windfall’ awards (above)
<i>PMPRB (Patent Act; Patented Medicines Regulations)</i>	Low: Price regulation a notional barrier to patentee profits	Broad: automatic for <i>all</i> patented products	Broad: Retroactive jurisdiction to patent pending period	Low: even a “slender thread” of a connection between patent and medicine entails price control jurisdiction	Affirms and codifies low specificity requirements (broad PMPRB jurisdiction) in <i>ICN v. Canada (PMPRB) 1996</i>	High: Forced price reduction; and, Historically escalating: As of Bill C-91 1993 repayment of up to two-times excess revenues collected

This analysis helps to illustrate how implementation can affect the notion of winning or losing a negotiation. It is not always what was agreed to under the duress of power asymmetry that matters. How an agreement is then shaped locally can have a

¹³⁹ McCurley and Lucas note: “Recent Case law has found that the strict product specificity requirements demanded by the minister and the courts for listing formulation and dosage form patents now also are applicable to claims for a medicinal ingredient... a claim for a medicinal ingredient must match the medicinal ingredient in the NOC specifically” (McCurley and Lucas 2014, 116-117).

¹⁴⁰ Ibid; Government of Canada, Health Canada (2015) “Guidance Document: Patented Medicines (Notice of Compliance) Regulations,” 15-101151-734 accessed December 2, 2015, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.pdf

meaningful impact on the ultimate force and effect of standards. For the standard-taker, winning is less about small negotiated concessions and more about retaining regulatory autonomy.

In summary, under the *PM(NOC) Regulation* the marketing approval of a generic was tied to the patent status of a brand drug. A generic manufacturer could simply allege a patent to be invalid to commence a 30-month PM(NOC) dispute. These disputes are usually followed by normal patent infringement or impeachment action that sometimes considers the same legal and factual issues as the PM(NOC) dispute. The incentives for generic companies to challenge patents are enormous. Generic companies apply for marketing approval before patent expiry for many high-value products leading to PM(NOC) proceedings at the Federal Court.¹⁴¹

This starts a lengthy and duplicative litigation process with clear financial implications for both brand and generic companies. The original public policy objectives of Bill C-91 and the patent linkage regulation reasonably sought to prevent patent infringement during litigation and secure Canada's access to the broader US market under NAFTA. Patent linkage was also an explicit balance against Bill C-91's "early working" provision for generic drug development during the patent period. Canada's perplexing patent litigation regime is an artefact of balancing competing domestic and international stakeholder interests in trade implementation. This has had a legacy effect for future trade agreements. For example, as discussed below, "dual litigation" is one of

¹⁴¹ In fact, according to an internal government analysis of the patent linkage process, generic companies made "claims of non-infringement in 52% of cases between 2004 and 2010." John Connell, Industry Canada, "Advice to the Senior Associate Deputy Minister," – Secret - CCM 227176, November 10, 2011.

the most contentious issues to be managed under the Canada-EU Comprehensive Economic and Trade Agreement (CETA).

Implementation and Sequencing Matter: NAFTA Implementation Act 1993

This section details NAFTA implementation and the regulatory amendments that followed it. It argues that timing was an important factor related to implementation. The government saw advantages to acting quickly in advance of US implementation and a pending general election in October of 1993.¹⁴² If the market power perspective offered a comprehensive explanation, these sequencing subtleties should not have mattered. However, NAFTA negotiator views suggest sequencing did matter. The section also traces changes that the Patented Medicines Prices Review Board made to strengthen its own guidelines in the NAFTA context.

On June 23, 1993 the *North American Free Trade Agreement Implementation Act* S.C. 1993, c. 44, Bill C-115 was given Royal Assent. In excess of 200 pages, the legislation contained many general provisions related to implementation including ministerial designation, Canada's section of a NAFTA secretariat, provisions for dispute panels, committees and scientific review boards, and powers of the Governor in Council regarding related regulations. The *Implementation Act* also amended parts of the *Patent Act* to address residual issues related to compulsory licences not addressed in Bill C-91 just a few months earlier. These changes were contained in Part II "Related and Consequential Amendments" the largest section of the legislation containing the Act-by-Act amendments required to implement NAFTA. Given that Bill C-91 had already made

¹⁴² Despite engaging in a regulatory amendment in 1994, the new government did not substantially alter the regime immediately following the election.

many changes, the *Patent Act* component amounted to just six pages of the *Implementation Act* (2061 – 2066). It is not entirely clear why some changes were made here and others in Bill C-91.

Principally, the *Implementation Act* empowered the Commissioner of Patents to authorize the use of patents on request of the federal or a provincial government (*Implementation Act*, s. 191.1 to repeal and replace s. 19 (1) of the *Patent Act*). It empowered the Commissioner to set the terms of use in accordance with several principles: a) an authorized use was to be limited in scope and duration; b) the use was to be non-exclusive; and c) the use was predominantly to supply the domestic market. (Ibid, at s. 19(2)). The patentee was afforded the right to be notified of the authorization (s. 19(3)); paid remuneration deemed adequate by the Commissioner taking into account the economic value of the authorization (s. 19(4)); apply for its termination once circumstances leading to the authorization ceased to exist (s. 19(5)); and, appeal any Commissioner decision to the Federal Court (s. 19.2) (*NAFTA Implementation Act 1993*).

Due to NAFTA and TRIPS, Canada could no longer provide “exclusive use” licences. These licences provided incentives for non-patent owners to make capital investments to develop a technology that was not being utilized by the patentee. Exclusive use was essentially the state transferring the monopoly incentive from the patentee to another party. Instead, the Commissioner would have to “endeavour to secure equality of advantage among the several licensees” and “reduce the royalties or other payments accruing to the patentee under any licence previously granted” (*Implementation Act*, s. 197(1-2) to repeal and replace s. 66(1b) and s. 66 (4c) of the *Patent Act*). The Commissioner would be subject to certain conditions when granting a licence. For

example, an applicant first had to make efforts to secure access to the patented subject matter on reasonable commercial terms (*Implementation Act*, s. 191.1 to repeal and replace s. 19.1(1) of the *Patent Act*). The *Implementation Act* also provided that “no patent shall be granted for any mere scientific principle or abstract theorem” (*Implementation Act* s. 192(3)). These were important parameters around how licensing could proceed and help illustrate the greatly diminished nature of the regime. The era of lucrative compulsory licensing so critical to the development and consolidation of the generic drug sector was over.

For both political and content reasons, Canada was keen on passing the NAFTA implementation bill and saw advantages to pre-empting US ratification. One advantage was that Canada could implement the deal with less scrutiny from the US than would have been the case if it waited for concurrent US ratification. According to John Weekes, Canada’s Chief NAFTA negotiator, Canada saw first-mover advantages to implementation:

It was interesting in the NAFTA, the Conservative government of Brian Mulroney decided that we should do the NAFTA implementation, pass the legislation implementing the NAFTA, before the US Congress did. Now I think they partly had in mind they weren’t quite sure what government would come after them... and what *their* approach might be in terms of implementing NAFTA... It actually worked very well because, basically, we did ours, we could have changed it, if we wanted to, later... we were then able to sit back and see what the United States did...the United States couldn’t say too much about what we were putting through our Parliament, because they had nothing in front of their Congress, so it was a little hard for them to be critical, which was useful too (John Weekes, Public Statement, January 18, 2016, Ottawa).

This statement is interesting for a couple of reasons. First is the observation that implementation needed to be completed in the dying days of the Progressive Conservative government for fear that implementation outcome could differ based on the

party in power. This speaks to an apparent flexibility that governments' have in implementing trade deals after negotiations are complete. Implementation can be *political* and is not simply a technocratic exercise where a negotiated outcome is easily transplanted into domestic law: the details and politics of treaty implementation matter.

This insight may be more or less true depending on the nature of the treaty and the constitutional approach governing treaties in relation to domestic law. With respect to treaty implementation, Canada is a “dualist” system like the UK, Germany, and most of the British Commonwealth (Halpérin 2014, 174). To greatly simplify, in dualist systems treaties are not directly part of domestic law so must be enacted into domestic legislation to have force and to be invoked (Jackson 1992, 315). This stands in contrast to “monist” systems such as the Netherlands, France, and Spain where treaties are notionally “directly applied” or “self-executing,” which entails that they can be invoked directly (Jackson 1992).¹⁴³ However, implementation provisions are also sometimes used in these systems and there are many national dynamics to consider when introducing complex new regulatory measures. The US system “stands somewhere in between” where some treaties are self-executing but have the status of a federal statute and thus can be overridden by subsequent federal statute, sometimes leading the US to violate its international obligations (Ibid, 320).¹⁴⁴ Comprehensive analysis of various international implementation dynamics is beyond the scope of this study. However, the point is raised

¹⁴³ This dichotomy should not be overstated as there are many nuances regarding the hierarchy of treaties in relation to domestic law, what it means to “invoke” (by whom), and policies and precedents related to treaty “self-execution” or “direct application.” For example, monist systems sometimes struggle to uphold direct application as exemplified by the case law on the General Agreement on Tariffs and Trade (GATT) in the Europe and Japan (Jackson 1992, 333-4).

¹⁴⁴ For a more detailed discussion, see Jackson (1992). See also the US approach to NAFTA Implementation: North American Free Trade Agreement Implementation Act. Public Law No. 103-182, 107 Stat. 2057, December 8, 1993 <https://www.gpo.gov/fdsys/pkg/STATUTE-107/pdf/STATUTE-107-Pg2057.pdf>.

here to highlight one of the many institutional issues that are a source of complexity and national path dependence. Ultimately, this supports the need for detailed process tracing specific to national laws. Further discussion on implications for future study is noted in the conclusion (Chapter 7).

The second insight from the negotiator quote above is that within this politicized environment, Canada pursued strategies related to *relative timing* of implementation that may have had an impact on ultimate domestic legislation. By getting implementation done first while the US dithered, Canada was able to somewhat depoliticize the environment for itself. It implemented its policies under diminished public scrutiny from the US. It is impossible to measure the impact of this timing strategy as even those closest to negotiations would have no way of assessing the counterfactual. Nevertheless, it is interesting that negotiators remember and extol the strategy and the importance of sequencing some 22 years after the fact.

A good illustration of this accelerated timeframe factor is found in the Regulatory Impact Analysis Statement attached to the *PM(NOC) Regulations*. The regulation appears to have been published without stakeholder comment on the specific text:

Primary stakeholders have been consulted on the principle of these Regulations prior to the passage of Bill C-91. However, given the importance of quickly giving effect to the new statute, consultations have not been undertaken on the text of the Regulations prior to their coming into force. Early notice was not given in the Federal Regulatory plan. As this is a new regulation the government will consult on its implementation, and make appropriate refinements if needed (*PM(NOC) Regulation*, Canada Gazette Part II Vol. 127, No. 6, SOR/93-133).

The expedited timeline in implementing NAFTA and the *PM(NOC) Regulations* thus removed one official opportunity for stakeholders to scrutinize the regulatory package in advance of its coming into force. It is also interesting that both the negotiator and the

regulator positions indicate future opportunities to amend or refine implementation outcomes later, if desired or if needed. This speaks to an autonomy and self-confidence on Canada's part that stands in contrast to dominant narratives of TRIPS and IP diplomacy as a hegemonic exercise of US imposition. Even those nations such as Canada with an overwhelming trade reliance on the US felt confident that they could shape the standards domestically on an *ongoing* basis. Being organized and acting quickly to establish domestic regulations was a key success factor that complemented trade and regulatory linkages within the bureaucracy.¹⁴⁵ Importantly, the manner of implementation provided future *flexibility*, even if that flexibility meant deferring important matters to the judicial branch. Moving first also entailed implementation under diminished scrutiny.

Beyond implementation autonomy, trade negotiators would also seem to consider time-related strategies associated with small powers catalyzing larger powers into action. Leveraging his NAFTA experience, John Weekes went as far as to suggest—with TPP Chief Negotiator Kirsten Hillman sitting beside him on a public panel—that Canada should consider using a similar advance implementation strategy on the TPP agreement in the context of US political delays and uncertainty:

I think you could make a strong argument that Canada has nothing to lose by ratifying [TPP] ahead of the United States, and several things to gain...potentially... If the TPP doesn't go anywhere in terms of ratification in the United States... and we should talk to the Japanese about this...I think it would actually enhance the prospect of the TPP getting through the US Congress.... The prospect that Canada might get the jump on the United States in the Japanese market on a whole range of agricultural commodities, for instance, would be something that actually might spur the US Congress into action (John Weekes, Public Statement, January 18, 2016, Ottawa).

¹⁴⁵ Discussed above in Chapter 3.

In other words, in addition to domestic content factors associated with sequencing of implementation, negotiators also consider foreign timing strategies. For example, they may consider how to enhance internal demand for implementation *within* the polities of their counterparty. In this speculative scenario market power still plays a role. Access to the large Japanese market is essentially the ‘bait’ that the smaller nation (Canada) would leverage to secure a ratification outcome by the larger party (the US). But missing from a purely market power explanation is the underlying *sequencing* of access to that market: the sequencing of an institutionalized trading relationship.

PMPRB Guidelines Amendment: New Price Maximum and CPI Restraints

In concert with 1993-1994 legislative amendments, the PMPRB built upon its own Guidelines that reflected its interpretation and definitions of excessive prices for patented products. As discussed, the initial Guidelines did not apply restrictive pricing tests to existing products and instead opted to only apply consumer price index (CPI)-based caps to future price increases. This decision entailed that some patented prices continued to be higher in Canada than their respective international median price. To further constrain prices, “after extensive consultations” in 1993, the pricing regulator

decided to revise the CPI-adjustment methodology and add the Highest [international price comparison] rule to the Guidelines. The Highest IPC rule states: the price of patented drug product will be assumed to be excessive if it exceeds the prices of the same drug products in all countries listed in the Regulations. It did not, however, decide to constrain the price of a category 3 drug by changing the [maximum non-excessive] test to be the lower of the [therapeutic class comparison] and the [maximum international price] (PMPRB, *Discussion Guide for the Consultations on the Board’s Excessive Price Guidelines* 2006, 18).

In other words, the pricing regulator further constrained potential prices of patented products through new rules under its administrative Guidelines. It added a powerful new

test regarding the highest allowable price. The institution evolved and built upon its rules in concert with the new trade-related IP context. Because its initial powers over specific pricing tests were fairly broad, the regulator had the power to further constrain patented drug prices separately from legislative or regulatory amendments. However, it elected for ‘balance.’ It would not allow a price above the international maximum, but neither would it force prices to an international minimum nor a “lower of” test. This has a considerable impact on allowable pricing in Canada. While Guideline pricing rules impact different products in different ways, generally, the selection of pricing tests and comparators can greatly impact the pharmaceutical market.

In addition to the new pricing maximum, the PMPRB also reformed its CPI methodology to further constrain price increases. The Board was particularly focused on products that had not taken past allowable price increases. It was concerned that the Guidelines did not prevent large one-time price increases for these products. To address this, the amended Guidelines specified that a price would be deemed to be excessive if

the cumulative change in price over a three year period is in excess of the cumulative change in CPI during the same period. In addition, any one-year price increase in the current pricing period may not exceed 1.5 times the forecast change in the actual CPI. In other words, if a patentee did not increase its price by the full allowable amount in the first or second year, it would be allowed to take some of the unused increase in the next year provided the annual increase was no more than 1.5 times the growth in the CPI (PMPRB, *Price Increases for Patented Medicines: Discussion Paper* 2005, 5).

This escalated the complexity of the PMPRB Guidelines somewhat and tightened the regulation of price fluctuations. This was made in the context of public concern over trade-related patent changes but was not connected to or negotiated in the trade context (Interview with a Canadian Official, December 5, 2015). The PMPRB’s ongoing role and importance had been affirmed. It amended its Guidelines to strike a balance between

patent holders and consumers within the Board's legislative mandate to prevent excessive prices.

Canada held a general election on October 25, 1993 where the governing Progressive Conservatives lost 154 seats (all but 2) and Prime Minister Jean Chrétien's Liberal government received a strong majority mandate. The election probably delayed PMPRB regulatory amendments somewhat. Amendments to the *Patented Medicines Regulations* were not adopted by Order in Council until November 1994, some 21 months after Bill C-91 Amending the *Patent Act*, 20 months after the *Patented Medicines (Notice of Compliance) Regulation* and 17 months after the *NAFTA Implementation Act*. However, following Bill C-91 and the PMPRB's own Guidelines changes there was apparently little need to substantially alter the *Patented Medicines Regulation*.¹⁴⁶ This was largely an administrative update that cleaned up the regulation without substantively altering the business environment for intellectual property owners. By 1994, pharmaceutical patentee R&D in Canada had spiked to 11.4% of sales, close to its peak of 11.7% in 1995 (PMPRB 2005). The PMPRB's Patented Medicines Price Index (PMPI) reporting metric that tracks aggregate pricing was declining moderately. Canadian patented drug prices had fallen below the international median of comparable prices for the first time (Ibid). For the time being, the PMPRB appeared to be working well to

¹⁴⁶ The November 1994 amendments were highly consistent with the original 1988 regulation (Patented Medicines Regulation, SOR/88-474, 1988 Canada Gazette Part II, 3921; Patented Medicines Regulation SOR/94-688, 1994 Canada Gazette Part II, 3851). The main changes were to 1) remove some of the transitional language contained in the original regulation and to make it more concise; 2) remove somewhat unclear qualitative information requirements such as descriptions of the manufacturing process and the extent to which medicines are "invented and developed" in Canada including phase III clinical trials; 3) update numerical references to the *Patent Act* as amended by Bill C-91; and 4) remove all of the specific forms to be submitted by a manufacturer from the actual regulation text. This left those details under the purview of the PMPRB and its Guidelines.

achieve its mandate. The new Liberal government did not see the need to alter its powers beyond what the previous Progressive Conservative government had enacted.

In summary, sequencing was an important element of NAFTA's implementation. The government wanted to head off US implementation so as to operate under diminished scrutiny from the hegemon. It also saw the value of legislating in advance of the upcoming general election. The deal was finally implemented just four months in advance of a sweeping change of government. This speaks to the fact that timing and the details of trade treaty implementation matter. In the context of these reforms, the PMPRB pricing regulator made its own changes to further constrain allowable patented drug pricing. Following the election, the new government did not substantively alter the new regime. It would have several years to study the impacts of the regime in advance of the statutory review of Bill C-91.

Stakeholder Coalition Achieves Modifications to Patent Linkage

Bill C-91 included a statutory review provision after four years.¹⁴⁷ This section examines changes to the C-91 regime under that review. It shows that an entrenched stakeholder coalition was successful in arguing for modifications to the patent linkage regime. The linkage regime was modified in 1998 to limit the length of injunction.¹⁴⁸ The section then looks to how these policy issues have emerged in contemporary debates and recent trade negotiations. This helps to illustrate the cumulative nature of trade and economic regulation and the impact of preserving future flexibility as part of implementation. New

¹⁴⁷ Section 14.(1) *Review of certain sections* provided a four-year review at committee House of Commons and/or Senate: "The committee shall undertake a comprehensive review of the provisions of the *Patent Act* enacted by this Act and shall, within one year after the review is undertaken...submit a report thereon, including such recommendations as the committee may wish to make pertaining to those provisions" (Bill C-91 1993, Canada Gazette III, Vol 16 (1), May 10, 1993, 32).

¹⁴⁸ The patent linkage regime was also amended in 2006 to restrict injunctions to one per product.

trade negotiations have picked up where previous deals left off. The implementation of the EU-Canada Comprehensive Economic and Trade Agreement (CETA) addresses issues that arise as a result of Canada's NAFTA and TRIPS implementation. Under CETA, a commitment was made to fully replace the patent linkage regime. This section helps to illustrate the theory over a longer time horizon.¹⁴⁹ Core domestic regulatory issues and interests persist and are expressed over multiple agreements and implementation processes.

Statutory Review of Bill C-91 1997-1998

The House of Common's Industry Committee commenced a review of C-91 in February 1997 (Meeting No. 42), launched with joint statements by the Honourable David Dingwall, Minister of Health and the Honourable John Manley, Minister of Industry.¹⁵⁰ This testimony was followed in subsequent days by presentations from the PMPRB Chair Robert Elgie and Executive Director Wayne Critchley; Health Canada officials; members of the *Pharmaceutical Manufacturers' Association of Canada* (patented industry), including presidents of major Canadian subsidiaries;¹⁵¹ and the *Canadian Drug Manufacturers' Association* (generic industry), including CEO's Leslie Dan (Novopharm) Berry Sherman (Apotex) as well as then VP Research and International Affairs James Keon. Keon was a former Canadian intellectual property policy official.

¹⁴⁹ This is important because the FTA and NAFTA were negotiated by the same government and were very close in time to each other. It is helpful to show how policies are addressed over multiple agreements, time, and different governments.

¹⁵⁰ House of Commons Standing Committee on Industry, "Minutes of Proceedings," Fifth Report: Section 14 of the Patent Act Amendment 1992 (C-91), accessed January 3, 2016, http://www.parl.gc.ca/content/hoc/archives/committee/352/indu/minutes/indu_issue-04_38-48/indu_04_min-e.html

¹⁵¹ Nelson M. Sims (Eli Lilly Canada) André Marcheterre (Merck Frosst Canada) and Paul Lucas (Glaxo Wellcome).

Following passage of Bill C-91, he went on to lobby for the generic drug sector and represented the sector's efforts to abolish or modify patent linkage.¹⁵² Another stakeholder voice was the Canadian Health Coalition comprised of critics of expanded pharmaceutical IP protections including Professor Joel Lexchin, advocate Michael McBane and other interested partners. Provincial governments were also consulted. Provincial drug plan budgets are significantly impacted by the extent of IP protection. The committee heard testimony from British Columbia, Manitoba, New Brunswick, Ontario and Saskatchewan.¹⁵³ With the exception of Ontario, which was concerned with drug costs but otherwise “saw balance” the C-91 approach, these provinces all actively supported *Canadian Drug Manufacturers' Association* (CDMA) positions.¹⁵⁴

One key CDMA position was actually to repeal the *PM(NOC)* patent linkage regulation all together. It threatened generic investment in Canada: “unless and until the regulations are rescinded, Apotex and others are unable to make further investments in the generic sector.”¹⁵⁵ The government was somewhat more realistic about Canada's trade commitments as limiting its range of options: “I don't think Canada can walk away

¹⁵²Keon had worked with Consumer and Corporate Affairs Canada from 1978-1994. He was a senior analyst from 1987-88 during the FTA, was promoted to Director of Intellectual Property from 1988 – 1991, and was acting Director General in 1994. Keon has been the President of the Canadian Generic Pharmaceutical Association (CGPA) (formerly Canadian Drug Manufacturers' Association) for more than two decades. Office of the Commission of Lobbying of Canada (2016), “Public Offices held: James Keon,” accessed January 21, 2016, <https://lobbycanada.gc.ca/app/secure/oc/lrs/do/lpoh?cid=548&lid=510062&sMdKy=>;

¹⁵³ House of Commons, Standing Committee on Industry, “Witnesses,” Fifth Report: Section 14 of the Patent Act Amendment 1992 (C-91) accessed January 3, 2016. http://www.parl.gc.ca/content/hoc/archives/committee/352/indu/minutes/indu_issue-04_38-48/indu_04_wit-e.html

¹⁵⁴ House of Commons, Standing Committee on Industry, “Summary of Testimony,” Fifth Report: Section 14 of the Patent Act Amendment 1992 (C-91) accessed January 3, 2016. http://www.parl.gc.ca/Content/HOC/Archives/Committee/352/indu/reports/05_1997-04/chap3-e.html

¹⁵⁵ Presentation of Barry Sherman, as quoted: House of Commons, Standing Committee on Industry, Fifth Report: Section 14 of the Patent Act Amendment 1992 (C-91) Chapter 3 “Summary of Testimony.” accessed January 3, 2016. http://www.parl.gc.ca/Content/HOC/Archives/Committee/352/indu/reports/05_1997-04/chap3-e.html.

from the World Trade Organization. I don't think Canada can walk away from NAFTA.”¹⁵⁶ As part of the lobbying effort surrounding Parliamentary review, generic industry stakeholder Leslie Dan delivered a speech in Toronto to the Economic Club of Canada in January 1997 (Dan 1997). Dan, the founder of Novopharm, then the largest generic producer in Canada by volume, critiqued Bill C-91 while extolling the virtues of compulsory licensing. His speech drew on nationalistic rhetoric and stoked fears of high drug costs and hospital closures:

[Parliamentary review of C-91] represents an important opportunity for the government of Canada to take action in order to balance the interests of Canadian consumers, the generic drug industry—which is primarily Canadian-owned—and those of the foreign-owned multinational companies which manufacture brand-name drugs...the current legislation, Bill C-91, favours excessively the large brand-name pharmaceutical manufacturers at the expense of Canadian consumers and the generic industry...(Dan 1997).

This is typical of the rhetoric and hard lobbying battles fought out in public between patented and generic industries on these issues. Dan made many good points but nowhere in his speech did he mention Canada’s trade commitments under TRIPS. He raised several issues related to implementation of C-91 that impacted Novopharm and the generic industry and iterated several key policy prescriptions. These included: 1) expedited review and repeal of section 55.2 of the *Patent Act*—this section empowered the Governor in Council to enact the patented medicines linkage regulations which put limits on Health Canada issuing an NOC to a generic manufacturer where it would infringe a patent;¹⁵⁷ 2) repeal s. 55.2 while maintaining “the right to do research prior to

¹⁵⁶ Testimony of David Dingwall, Minister of Health: Ibid.

¹⁵⁷ While not elaborated in Dan’s speech, Section 55.2 (4) states “The Governor in Council may make such regulations as the Governor in Council considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1), including, without limiting the generality of the foregoing, regulations: (a) respecting the conditions that must be fulfilled before a notice, certificate, permit or other document concerning any

patent expiry;”¹⁵⁸ 3) no patent term extension;¹⁵⁹ 4) an export exemption incorporated into the *Patent Act*; 5) allowing generic products to have similar size, shape and colour to brand drugs; 6) “restore the retroactivity of licenses which were issued between December, 1991 and February, 1993 and which were taken away;” and, 7) a general preference that patent protection only offer five to ten years exclusive market monopoly (Dan, The Empire Club of Canada Address, January 3, 1997). Regardless of any merits to these points, some would put Canada offside of the TRIPS Agreement.

After hearing from 140 witnesses over a few months the Liberal-controlled committee made recommendations in April 1997. The Committee “found this policy area to be one of the most contentious and difficult ones facing the Canadian government.”¹⁶⁰ Given some of these concerns the committee recommended that government “re-visit the regulatory regime associated with Bill C-91” among other recommendations including improving the PMPRB’s statistical reporting.¹⁶¹

The group of stakeholders and provincial governments proved to be a powerful interest coalition. In 1998, the period of automatic injunction in patent linkage was

product to which a patent may relate may be issued to a patentee or other person under any Act of Parliament that regulates the manufacture, construction, use or sale of that product, in addition to any conditions provided for by or under that Act; (b) respecting the earliest date on which a notice, certificate, permit or other document referred to in paragraph (a) that is issued or to be issued to a person other than the patentee may take effect and respecting the manner in which that date is to be determined;... (e) generally governing the issue of a notice, certificate, permit or other document referred to in paragraph (a) in circumstances where the issue of that notice, certificate, permit or other document might result directly or indirectly in the infringement of a patent” (*Patent Act* 1985).

¹⁵⁸ As discussed above, this refers to “early working” or “Boler provisions” found in section 55.2(1) of the *Patent Act*: “It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product” (*Patent Act* 1985).

¹⁵⁹ This likely referred to Dan’s opposition to eliminating the “phase in” of 20-year patent life that would be subject of the US WTO challenge. This was ultimately removed in 2001 under Bill S-17.

¹⁶⁰ House of Commons, Standing Committee on Industry, “Recommendations,” Fifth Report: Section 14 of the Patent Act Amendment 1992 (C-91), accessed January 3, 2016.

http://www.parl.gc.ca/Content/HOC/Archives/Committee/352/indu/reports/05_1997-04/rec-e.html

¹⁶¹ Ibid.

reduced to 24 months (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, Canada Gazette II, 132(7), 1998). Canada's stockpiling provision would be maintained. The lobbying effort was perhaps as successful as possible while remaining NAFTA and TRIPS compliant, notwithstanding that stockpiling was later ruled offside of TRIPS at the WTO. The change to patent linkage further exemplifies the flexibility Canada had in implementing and subsequently modifying its trade-related IP reforms. This was possible due to Canada's legislative system where many important details are enacted in regulation and elaborated in case law or interpretive guidance following the implementing legislation.

The Minister of Industry John Manley recognized the reality of Canada's flexibility regarding linkage regulation in response to a question at committee. Mr. Brien, MP from Témiscamingue, asked Manley: "To your mind, are the regulations part of the international commitments? Is it your opinion that the regulations cannot be amended without violation of international agreements?" In response, Manley noted:

The ability to manufacture pharmaceutical products before the expiry of patents, which plays in favour of generic drug companies, and the regulations, which favour international companies, are not provided for in the international commitments. Therefore, it is possible to abolish regulations. That is not an international commitment.¹⁶²

Patent linkage was, of course, not *specifically* required under TRIPS and NAFTA. However, eliminating it would require other interlocutory measures during patent litigation. The Liberal government decided to limit but not abolish the regime. Nevertheless, the flexibility to alter or abolish the regulation independent of trade treaties remains an important source of Canadian autonomy.

¹⁶² Hon John Manley, Testimony Before the Standing Committee on Industry, Monday, February 17, 1997, accessed June 11, 2016
http://www.parl.gc.ca/content/hoc/archives/committee/352/indu/evidence/42_97-02-17/indu42_blk-e.html

Patent Term Restoration, Right of Appeal, and Dual Litigation in Contemporary Debates

The legacy of the linkage regulation would leave an indelible mark on patent disputes in Canada as well as future trade negotiations. The primary impact was the emergence of a system the generic industry has termed “dual litigation.” Most lucrative products in Canada are challenged through the PM(NOC) stream first and often litigated a second time through a full patent infringement or patent impeachment action. This entails that the same patents are often before the Federal Court on two separate occasions, sometimes on much of the same factual basis. Ending “dual litigation” has been a central point of generic industry advocacy, particularly through trade deals such as the Canada-EU Comprehensive Economic and Trade Agreement (CETA). Conversely, creating an effective *right of appeal* under PM(NOC) was also a central point of patented industry advocacy in these negotiations. Patentees also want Canada to enact equivalent measures to the parts of the *Hatch-Waxman Act* that Canada did not pursue in the 1993-94 amendments, namely, a system of patent term restoration.

Patent term restoration (PTR) offers a period of protection “to compensate patent holders for marketing time lost while developing the product and awaiting government approval.”¹⁶³ The US had introduced this in 1984 under the *Hatch-Waxman* Amendments to the Federal *Food, Drug, and Cosmetic Act*, which instituted up to maximum five years

¹⁶³ “[I]n order to stimulate product development and innovation, Congress in 1984 enacted Title II of the *Drug Price Competition and Patent Term Restoration Act* (Public Law 98-417) to extend patent life to compensate patent holders for marketing time lost while developing the product and awaiting government approval. Title II of the Act created a program whereby patent holders whose patents claim a human drug product, medical device, food additive or color additive could recoup some of the lost patent time... The regulations governing the Patent Term Restoration program are located in the Code of Federal Regulations, 21 CFR Part 60.” Federal Drug Administration, “Frequently Asked Questions on the Patent Term Restoration Program,” Accessed July 15, 2016, <http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm>

of supplemental protection. This protection was capped so that total patent life including extension could not “exceed 14 years from the product’s approval date.”¹⁶⁴ US patentees could apply for PTR and eligibility would be determined by the Commissioner of Patents, US Patent and Trademark Office (USPTO). The Commissioner determines the period of extension based on the patent time expended during a “clinical testing phase” and a regulatory “approval phase.” The latter is determined by the length of a product’s regulatory review as measured by FDA and published in the Federal Register. Under 35 U.S. Code § 156(c) the patentee can receive one-half (50%) of the number of days under clinical testing phase, which is the difference between the patent date and the commencement of regulatory review by FDA. The patentee must act with “due diligence” to efficiently bring the product to market and any unreasonable delays are subtracted from the restoration period (35 U.S. Code § 156(c)(1)).

The USPTO maintains a list of supplemental PTR certificates granted.¹⁶⁵ For the purposes of patent linkage, the FDA maintains its “Orange Book” of relevant regulatory approval dates and patent expiry dates. On application for regulatory approval (Abbreviated New Drug Application, ANDA), a generic applicant in the US must declare that the product will not infringe any patents on the Orange Book list.¹⁶⁶ US marketing approval will not be granted until related patents have expired. Based on an analysis of the database maintained by the US Patent and Trademark Office (USPTO), PTR is typically much shorter than the maximum 5 years available, with an approximate simple

¹⁶⁴ Ibid. See 35 U.S. Code § 156(c) (3).

¹⁶⁵ USPTO, “Patent Terms Extended Under 35 USC §156,” accessed July 15, 2016, <http://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156>

¹⁶⁶ Specifically: “That the drug has not been patented; 2) That the patent has already expired; 3) The date on which the patent will expire, and the generic drug will not go on the market until that date passes; or 4) That the patent is not infringed or is invalid” (Ferriter 2007).

average of 2.7 years for the more than 600 patents granted PTR as of July 2014.¹⁶⁷ This constitutes a major addition to US patent life. Canada only partially imported the *Hatch-Waxman* model by creating its own regulatory linkage mechanism with a 30-month injunction period but no patent term restoration.

Another example of where Canadian amendments did not go as far as US rules were the damages available to patentees when patents are infringed. The US provides “enhanced damages” for “willful infringement.” This protects against abusive or speculative activity of generic manufacturers by tripling the damages for willful patent infringement.¹⁶⁸ The Government of Canada highlighted this important difference in an information package associated with the retrospective review of Bill C-91.¹⁶⁹

Major EU-based pharmaceutical producers have a similar goal to the US in pushing Canada to bolster its intellectual property protection regime. Given that NAFTA negotiations produced patent linkage with no PTR, the EU in 2007-08 effectively picked up where NAFTA left off through the CETA negotiations.¹⁷⁰ Key EU objectives for the CETA directly address patent measures implemented in the NAFTA era. These included a patentee right of appeal in PM(NOC) patent linkage proceedings and a Hatch-Waxman-style patent term restoration (PTR) regime. Under CETA, Canada conceded to provide a maximum of only two years of PTR or “sui generis” protection—less than the 5 years provided by the US and EU. Canada has not yet released all details on how this will be calculated but noted in its 2014 political summary of the agreement that the “reference

¹⁶⁷ Author calculation. Per the *Act*, this includes drugs and some non-drug patents.

¹⁶⁸ Government of Canada, “Review of the Patent Act Amendment Act, 1992 (Bill C-91): Information” February 1997, 10, Industry Canada, Distribution Services, Ottawa, ON.

¹⁶⁹ *Ibid.*

¹⁷⁰ This is explored further in Chapter 5. For a high-level chronology of CETA and its early years see: Government of Canada, “Chronology of events and key milestones,” accessed July 15, 2016, <http://international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/understanding-comprendre/chronology-chronologie.aspx?lang=eng>

points” will include the “filing of the application for the patent and the first authorization to place the product on the Canadian market” (Government of Canada 2014, 19).

Canada made other CETA-related commitments to the generic industry that directly address the legacy of TRIPS and NAFTA. One is “to ensure that litigants are afforded effective rights of appeal, which gives scope for Canada to end the practice of dual litigation” (Ibid). At the conclusion of CETA negotiations, details regarding how this will be implemented were to be announced. The commitments were to “ensure all litigants have equal appeal rights”; take “inefficiencies out of the system”; and guarantee “an effective appeal for brands and more certainty for generics” (Ibid). It should be noted that like NAFTA and TRIPS, no specific commitments on patent linkage were reflected in the actual CETA text. The Canadian CETA implementation legislation, Bill C-30, passed through Parliament in early 2017 with these changes to patent linkage still to be determined in regulation.

The addition of dual litigation to the CETA package is a critical example of how trade agreements can come with regulatory responses not part of the agreement, in this case, concessions to benefit the generic drug sector. This is illustrated in an internal government briefing note obtained under the *Access to Information Act*:

In March 2014, the members of Canada’s Research-Based Pharmaceutical Companies (Rx&D) signed a letter to the Prime Minister requesting consultations to ‘ensure that the dual litigation issue does not undermine the positive steps forward’ in CETA. In their view, dual litigation was not part of the negotiated outcome between Canada and the European Union, emerging only after negotiations were concluded.¹⁷¹

¹⁷¹ Mitch Davies, Acting Assistant Deputy Minister Strategic Policy Sector, Industry Canada, Advice to the Deputy Minister of Industry – Secret – CCM 270436 “Consultations on the Pharmaceutical Provisions in the CETA” October 21, 2014.

This shows how the government has considerable scope to shape the impact of actual trade commitments—an innovator right of appeal as a concession to the EU—with related regulatory measures (ending dual litigation) that benefit domestic producers. It is unclear if EU negotiators knew about this concession, which had been part of discussions with the generic industry as early as February 2012.¹⁷² In fact, the generic industry proposed specific treaty language that would prevent dual litigation to senior officials in October of 2011.¹⁷³ Either this language was not proposed by Canada to the EU, or if it was, it did not make it into the final negotiated agreement. Either way, the brand industry position that this was not part of the negotiated outcome would seem to be justified.

A different government is responsible for implementing the trade deal than the one that made these regulatory commitments. As such, there are many possibilities for how the NAFTA linkage regime will evolve under CETA implementation. Given the history explored above, trade commitments are likely to be implemented with considerable deference to institutionalized interests and build off the existing regulatory regime.

Conclusion

Patent linkage was the most US-style provision implemented during the TRIPS/NAFTA era. It directly replicated the 30-month stay for patent disputes and tied generic market

¹⁷² Richard Dicerni, Deputy Minister, Industry Canada, Advice to the Minister – Secret - CCM 230912 “Meeting with the Canadian Generic Pharmaceutical Industry Association (CGPA).” “Advice: We recommend that you thank CGPA for its continued engagement with Industry Canada on the CETA negotiations, and inform them that officials are reviewing their recent proposals to end dual-litigation and address generic damages.” In this ministerial advice the government noted the differential litigation costs between PM(NOC) proceedings (\$2-6 million) and full disputes under the Patent Act (\$20 million) and that as of February 2012 there had been 53 cases where drug patents had been litigated under both processes.

¹⁷³ Communications from Canadian Generic Pharmaceutical Association to Senior Industry Canada Official, October 20, 2011.

approval to brand patent status. Patent linkage was a commitment that went beyond TRIPS and was not codified in NAFTA. On the surface, Canada's introduction of the policy would seem to be most likely to support the alternative market power hypothesis. However, Canadian officials actually secured an important win by keeping this intellectual property policy out of trade treaties. This preserved domestic sovereignty and Canada's flexibility to reduce or otherwise modify IP protections in the future. Canada's patent linkage regime also substantively deviated from the US *Hatch Waxman Act* and Canada provided no patent term restoration as part of its NAFTA-era reforms.

Canada reduced its IP protections following intensive stakeholder lobbying. Under a four-year statutory review mechanism incorporated into Bill C-91, a powerful stakeholder coalition was successful in arguing that Canada modify patent linkage to be less protective. As discussed, this coalition was itself the product of past Canadian policy choices, namely, the British-style system of compulsory licensing.¹⁷⁴ Compulsory licensing produced a powerful generic drug sector in Canada, which has left an indelible mark on Canadian IP and innovation policy. Supported by consumer advocates, academics and some provincial governments, the generic drug sector has resisted the patent linkage policy. The generic industry continued to argue for its full repeal in the CETA context. These efforts have been successful with significant reform of the patent linkage regime pending. Learning from the TRIPS and NAFTA examples, we can predict that the details of implementation will critically shape the regime going forward. These insights should be tested further in various dualist and monist settings and for different treaty types and levels of complexity.

¹⁷⁴ Discussed above. See Chapter 3.

The sequencing of NAFTA implementation seems to have played a role in allowing Canada to regulate under diminished scrutiny from the US. This strategy accelerated the urgency of implementation. Regulators also deferred to the courts on important policy issues such as the assessment of damages. Additionally, a comparison of regulatory provisions shows Canada's efforts to constrain IP protections and provide regulators with expansive powers.

While advocates of weak IP protections may support the self-constraining nature of Canadian policy environment, institutional layering may have more challenging implications for other areas of international regulatory cooperation. It may not always produce desirable outcomes. In almost every measurable way, Canada's innovation and IP policies have failed. Business R&D investment in Canada continues to lag. The fragmented nature of the Canadian federal system of government has produced some of the highest per capita expenditures on patented and generic prescription pharmaceuticals in the OECD (PMPRB, *Guidelines Modernization Discussion Paper* 2016; see discussion Chapter 7). The Canadian environment is overly litigious, fraught with duplication, and lacks predictability. This is an unfortunate side effect of institutional layering. It negatively impacts both brand and generic sides of the sector and they have argued for reform (Government of Canada 2013). As will be explored in the next chapter, the clash of domestic and international regulatory standards under NAFTA and TRIPS has produced a system of patent litigation that faces many challenges. This was partially a result of the patent linkage compromise.

Chapter 5 - Institutional Feedback: The Legal Dimension

This chapter examines legal and case law developments following TRIPS and NAFTA implementation in Canada. It shows how Canadian judicial institutions have narrowed the definition and scope of patentable utility in the post-TRIPS era. This constraint on the practical extent of market exclusivity provided by the intellectual property regime was a product of Canadian institutional capacity and history. Market power is not well suited to examining legal minutia within the black box of the state and its judicial institutions. When idiosyncrasies in domestic adjudication processes arise, we would expect to see bilateral pressure and prompt domestic resolution. However, US advocacy efforts to pressure Canada to address this legal development are shown to be ineffective. Furthermore, Canadian resistance in this policy area has subsequently shaped future international trade and regulatory standards.

The chapter begins by comparing TRIPS and NAFTA language on patent utility to Canada's *Patent Act* as amended under those agreements. It provides a plain-language overview of some fairly complex case law termed the "promise doctrine" or "promise utility doctrine." Under this doctrine, the court essentially interprets what the patent language "promised" the technology would be useful for. In some cases, the court reconstructs what utility could have been "soundly predicted" at the time of patent application (Gold and Shortt 2014, 16; Siebrasse 2014, 21; Wilson 2014, 5, 11). Several lucrative patents have been ruled invalid under this doctrine.¹⁷⁵ It has become "almost

¹⁷⁵ Invalidation is used here broadly to include summary judicial rulings that render patents effectively invalid under Patented Medicines (Notice of Compliance) Regulations (PM(NOC)) proceedings

invariably the standard for assessing utility of a pharmaceutical patent” in the Canadian system (Siebrasse 2013, 1). The chapter identifies institutional and case law sources for the promise doctrine’s development, and then traces subsequent case law and the political fallout. The chapter explores political pressure for amendment from the United States and its corporations and finds that judicial standards remain resilient.

The chapter concludes that to fully understand international regulatory standards, scholars must consider the practical intersection of global standards and domestic institutions. Implementation must be conducted with precision, as new international standards tend to build on a prior institutional framework in a layering or cumulative fashion. Furthermore, sequencing and historical precedent can be important to final policy outcomes. The policy evolution illustrates the utility of historical institutionalism in comparison to alternative theoretical approaches.

Patent Invalidation Under the Promise Utility Doctrine

This section argues that Canadian judicial institutions have mitigated the full impact of TRIPS and NAFTA by leveraging historical practice and case law to set more onerous standards for patentability in Canada. This was possible because Canada did not directly replicate some TRIPS and NAFTA language when implementing those treaties into domestic law via amendments to the *Patent Act*. Canadian judicial institutions retained and asserted considerable authority over the scope of patentability.

International IP regimes help to harmonize standards. This harmonization does not always lead to consistent outcomes. TRIPS enshrined in treaty 20 years of patent

before the Federal Court. PM(NOC) proceedings are a primary source of promise doctrine case law. Henceforth, the term invalidation is used to refer to successfully challenged patents in both PM(NOC) and full patent infringement streams of litigation.

protection applied to all Canadian patents. This standard was actually implemented as part of the Canada-United States Free Trade Agreement package (the FTA). Canada's membership in the Patent Cooperation Treaty (PCT), effective January 1990,¹⁷⁶ provided patentees with the option of one common submission point for international patent applications. PCT membership facilitated simultaneous filing in 148 treaty member countries.¹⁷⁷ This allowed Canadian patent reviewers to rely heavily on common international search report information (Wilson 2014, 4).¹⁷⁸ In other words, patent examiners in Canada often rely on international standards and existing international approvals when granting a Canadian patent (Ibid). Despite international process and standards harmonization under TRIPS and the PCT, international treaty language did not bind parties to a unified definition of what would constitute a useful invention or "patent utility."¹⁷⁹

Under TRIPS Section 5 (Patents) Article 27, the definition of patentable subject matter is broad and linked to industrial application: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."¹⁸⁰ These

¹⁷⁶ World Intellectual Property Organization. 2013. "Patent Cooperation Treaty Applicant's Guide, Annex A," accessed February 27, 2015, http://www.wipo.int/pct/guide/en/gdvoll/annexes/annexa/ax_a.pdf

¹⁷⁷ World Intellectual Property Organization. 2014. "Protecting your Inventions Abroad: Frequently Asked Questions About the Patent Cooperation Treaty (PCT)," accessed February 27, 2015, http://www.wipo.int/export/sites/www/pct/en/basic_facts/faqs_about_the_pct.pdf

¹⁷⁸ Murray Wilson, former Chair of both Canada's Patent Examination Board and Patent Appeal Board, has described the reliance of Canadian patent officers on international approvals and how PCT material facilitates the application process: "In my experience, the fact that the U.S. or U.K. patent office had granted a patent to an identical invention was of some influence to Canadian patent examiners. International patent applications filed under the PCT were also easier to review because they included a search report, which meant the examiner did not have to spend as much time searching the prior art" (Wilson 2014, 4).

¹⁷⁹ World Trade Organization, *TRIPS* Agreement, 331 accessed February 28, 2014, https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

¹⁸⁰ Trade Related Aspects of Intellectual Property Protection (TRIPS) Agreement, at 331, accessed April 2, 2015, https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm

terms are defined in TRIPS with some latitude to the patent-granting member country: “‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively.”¹⁸¹ This broad TRIPS language left considerable scope for domestic review and interpretation with respect to the determination of obviousness and utility.¹⁸²

In a similarly broad fashion, Canada’s *Patent Act* defines invention as “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.”¹⁸³ Importantly, the specific definition found in TRIPS was never replicated in Canadian law. Per the domestic flexibility entailed by the language “may be deemed by a member,” the term “useful” was not made synonymous with ‘capable of industrial application.’ Canadian courts have capitalized on this broad scope by reaching back into case law precedent to impart a Canada-specific notion of what constitutes a valid patent.

Patent challenges and invalidation are constantly in a state of flux and patents are routinely invalidated in many countries. However, for the international IP regime to be efficacious, there should be considerable convergence of actor expectations around common international patent applications and general consistency across jurisdictions. For example, on balance one would expect the same ‘good’ patents to be upheld and frivolous patents not granted or invalidated. To the contrary, several lucrative patents

¹⁸¹ Ibid.

¹⁸² Most patent systems do not allow patents on ideas that would be ‘obvious’ to a person skilled in the art. Legal standards for the determination of obvious vary by legal system and existing case law.

¹⁸³ *Patent Act*, Statutes of Canada 1985, 2, accessed April 2, 2015, <http://laws-lois.justice.gc.ca/eng/acts/p-4/page-1.html>

have been invalidated in Canada under “promise doctrine” case law.¹⁸⁴ This has not been seen under the equally litigious US system or elsewhere in Europe.

The promise doctrine technically impacts *all patented technology* but has had practical implications primarily for the pharmaceutical sector. This was facilitated by a strong Canadian generic export sector with the resources to endure lengthy and costly litigation and routinely challenge the patents of US and EU multinationals. The invalidations often impact a subset of pharmaceutical patents called “selection patents” where a broad “genus” or class of compounds is first patented, and then as useful applications are developed, selections from that genus are subsequently patented (Gold and Shortt 2015, 40). This is a common but contentious practice that is sometimes framed as double patenting or “evergreening” by the generic industry.¹⁸⁵ Alternatively, patentees argue this is an essential component of the patent system providing incentives to advance research and conduct clinical trials. The Supreme Court of Canada (SCC) has upheld this view and the general importance of selection patents. The court dismissed the notion that selection patents *ipso facto* constitute double patenting or evergreening. It has affirmed the importance of the doctrine of selection patents on the basis of recognizing improvements made: “selection patents encourage improvements over the subject matter of the original genus patent because that selection does something better than or different

¹⁸⁴ See Gold and Shortt 2014, especially page 2 for a detailed review of the “small but growing” literature on the “promise doctrine” in Canadian patent law.

¹⁸⁵ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* [2008] SCC 61, SCC docket 31881, accessed May 20, 2015, <https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2575/index.do> As defined in Chapter 4, “Evergreening” is a general term applied to various patenting strategies that attempt to prolong effective patent life of a compound. For an alternative definition and discussion see US Congressional Research Service Report (Thomas 2009): Evergreening is “a potentially pejorative term that generally refers to the strategy of obtaining multiple patents that cover different aspects of the same product, typically by obtaining patents on improved versions of existing products” (Thomas 2009, 2).

from what was claimed in the genus patent.”¹⁸⁶ However, the courts have set onerous standards for when such selections can take place through heightened evidence requirements. These evidence requirements apply at the time of the patent application.

While TRIPS language focuses on commercial application, Canadian courts have adopted a much narrower definition of utility based on its interpretation of the promise of the patent. Selection patents are particularly impacted because patentees *must* specify how selections are distinct from the genus:

Patent applications may contain promises for a variety of reasons. Sometimes, a particular degree of usefulness is at the core of the invention.... Another case, that of “selection patents”, arises where a patent has already been granted for a broad class of compounds (or “genus”)... A party may seek a second patent for a sub-species of that genus on the basis that it has discovered that the sub-species (or “selection”) has a surprising and non-obvious advantage over other members of the genus. Otherwise, the patentee of an original “genus” patent would be able to “evergreen” its original patent monopoly, through subsidiary patents for sub-classes of that very same invention.¹⁸⁷

The Canadian case law emerges from this selection patent problem but impacts the entirety of what is patentable and what evidence is required at the time of the patent application. Because TRIPS/NAFTA implementation did not alter domestic laws with respect to the specific technical definitions of utility, judicial institutions were positioned to define this going forward. The courts creatively applied historical precedent to exclude certain patents, and thus shape the standard to reflect local practices and norms.

A normative factor potentially impacting the evolution of the promise doctrine is the sentiment in Canada against “evergreening.” There is a notion that only one period of

¹⁸⁶ Ibid.

¹⁸⁷ Government of Canada, Statement of Defense, *Eli Lilly v. Canada*, No. UNCT/14/2, June 30, 2014, 11,12, accessed May 20, 2015, <http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli-statement-declaration.aspx?lang=eng>

exclusivity per drug is just, regardless of any research effort that may have gone into selection of a particular subset of the genus. Evergreening is possible in many international jurisdictions and some argue that it has considerable associated costs (Vernaz et al. 2013). As noted by Jonathan Darrow, while critics see only “minor variations” these patenting strategies do not actually extend the patent life of the original product:

suggesting that [variations] extend the effective patent term of the original product involves a bit of analytical [sic] sleight of hand.The old drug, which is no longer subject to patent protection, is in the public domain. Although drug companies have obtained a new patent, the patent on the original drug product hasn't been extended at all (Darrow 2010, 6).

Even when the new variation is patentable, that does not mean that governments want to grant multiple patent linkage injunctions on the same molecule. While only one of several potential evergreening scenarios, multiple injunction periods under US and Canadian patent linkage provisions was seen as a problem (see chapter 4) and caused both countries to amend them in 2003 and 2006 respectively. Beyond regulatory patent linkage, Canadian courts still had to grapple with how to manage the patentability of new uses and secondary selections from an already patented genus.

Foundations in Case Law

In addition to treaty implementation, previous case law was an important source of the promise doctrine's development. This section explores these sources. It defers to legal experts and the extant legal literature on the promise doctrine to inform its temporal analytical parameters. The common law roots of the promise doctrine can be traced to *Consolboard Inc. v. MacMillan Bloedel Limited (1981)* regarding some elements of the

utility definition (Siebrasse 2014, 4). It may reach back even further to the British House of Lords in *Hatmaker v. Joseph Nathan & Co (1919)* regarding reference to a specific “promise” of a patent (Gold and Shortt 2015, 39). Building on *Consolboard (1981)*, the first major case to codify the test for the promise doctrine was the Supreme Court of Canada (SCC) ruling in *Apotex Inc. v. Wellcome Foundation Ltd., (2002)*. Legal scholars and patent office practitioners have identified a series of cases beginning in 2005 that are importantly shaped by the Supreme Court *Wellcome (2002)* ruling and precipitated changes in Canada’s official manual for patent examiners (Siebrasse 2013; 2014; Wilson 2014, 6). As such, this analysis starts process tracing on the *Wellcome (2002)* case as a reasonable “critical juncture” or “point at which an institution or practice was contingent or open to alternative paths, and actors or exogenous events determined which path it would take” (Bennett and Checkel 2015a, 26).

This case started in 1998 around the same time as the generic industry was fighting for amendments to the PM(NOC) patent linkage regulation. At that time, generic drug giant Apotex made the decision to take on a high profile patent dispute regarding one of the first available drugs to have some success in treating human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS). At issue in *Wellcome (2002)* was an existing drug *zidovudine* commonly referred to as AZT. In the 1960s, AZT had been investigated unsuccessfully as a potential chemotherapy agent. During the height of the AIDS crisis, the Wellcome Foundation and its partner company Glaxo/Wellcome, which were not the compound’s original inventors, identified a new use for AZT in the treatment and prophylaxis of AIDS. Glaxo/Wellcome called the drug Retrovir and was granted a patent. Apotex wanted to market a generic

version of AZT so challenged the patent in both the Federal Court and the Federal Court of Appeal. Both upheld the patent. Apotex appealed to the Supreme Court on the basis “that the necessary utility had not been established as of the priority date of the patent, that the [patent] claims covered more than the invention (prophylactic properties as well as treatment properties).”¹⁸⁸ The SCC ultimately disagreed and also upheld the patent. However, the SCC did feel the need at that time to conclusively spell out acceptable parameters for “new use for old compounds” and rule on the statutory requirements for invention and patent utility.

Wellcome (2002) spelled out the test that would set the legal standard and would come to have implications for Canada’s international relations:

Utility is an essential part of the statutory definition of an “invention” [189]. The inventor must be in a position to establish utility as of the date the patent is applied for, on the basis of either demonstration or sound prediction based on the information and expertise then available. Where the subject matter of the patent is a new use for an old chemical compound, it is not enough that the invention is reduced to a definite and practical shape by the formulation of a written or oral description. Nor is it enough for a patent owner to be able to buttress speculation with post-patent proof. If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, there is evidence of lack of utility in respect of some of the area covered...

The doctrine of sound prediction has three components. Firstly, there must be a factual basis for the prediction. Secondly, the inventor must have at the date of the patent application an articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis. Thirdly, there must be proper disclosure. The soundness (or otherwise) of the prediction is a question of fact. The doctrine of sound prediction, in its nature, presupposes that further work remains to be done. Care must be taken, however, that the doctrine is not abused,

¹⁸⁸ *Apotex Inc. v. Wellcome Foundation Ltd.* [2002], SCC S.C.R 4 docket 28287, at 154, accessed February 20, 2014 <https://scc-csc.lexum.com/scc-csc/scc-csc/en/2020/1/document.do>

¹⁸⁹ Note the statutory definition of “invention” cited in the decisions is that found in Canada’s *Patent Act*. This is cited above in this chapter.

and that sound prediction is not diluted to include a lucky guess or mere speculation.¹⁹⁰

Under this test, an inventor must have proof of utility at the date of the patent application or be able to ‘soundly predict’ it. By defining the utility test as it has, the SCC effectively heightened the disclosure and evidence requirements to establish that an inventor’s prediction about utility was sound. The ruling does acknowledge that “further work” or studies on an invention can be completed at a future date. However, the disclosure requirements can still be highly challenging in the context of the normal drug development process. For obvious practical and competitive reasons, clinical trials are almost exclusively conducted *after* the patent application.

Here we see the Supreme Court adopt a Canada-specific standard for evidence to establish utility. The passage also explicitly excludes post-patent filing evidence for sound prediction cases (Siebrasse 2014, 16). Often, the court does allow post-filing evidence, for example, to establish non-obviousness and lack of utility (Ibid). For sound prediction cases, it is not enough to simply show evidence of clinical development or commercial success after the patent application. Had the SCC allowed post-filing evidence, the entire promise doctrine issue may not have developed post-2002.

There is some scholarly disagreement on the general ‘newness’ of this doctrine. Those who disagree with Siebrasse’s (2014) characterization of the promise utility doctrine as something fundamentally *new* may also disagree with the characterization of *Wellcome (2002)* as a “critical juncture.” Some argue that non-pharmaceutical cases as early as 1947 also dealt with the “promise of the patent” (Gold and Shortt, 2014, 56). Notably, Gold and Shortt argue that Siebrasse incorrectly dismisses the “promissory

¹⁹⁰ *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] *supra*, at 154.

aspects” of the judgment in *New Process Screw Corp v. PL Robertson Manufacturing Co (1961)* and that he instead privileges the court’s application of a “scintilla” (of utility) standard (Gold and Shortt 2014, 56).¹⁹¹ Siebrasse counters that Gold and Shortt obfuscate the issue by conflating the specific promise doctrine with other doctrines associated with invalidation including obviousness, sufficiency and overbreadth (Siebrasse 2014b, 2). *New Process Screw (1961)* is not part of the promise doctrine because “the promise is made in the claims, not in the disclosure” (Ibid, 53).¹⁹² This is clearly a point of disagreement between legal experts who appear on opposing sides of the patent utility issue and the present analysis does not aim to settle the dispute. This important disagreement, however, does support the methodological point that the decision when to start and stop process tracing can be somewhat subjective.

Despite this potential subjectivity, there seems more than enough evidence of a compelling juncture on *Wellcome (2002)*. This was an actual pharmaceutical IP case where Canada’s highest court had a *clear choice* to accept or reject utility-specific admissibility of evidence. And the decision had substantial implications for Canada’s treatment of evidence going forward. This case is, in fact, the basis for Gold and Shortt’s own comparison between the Canadian system and the US system regarding incentives for utility-based litigation. They argue that incentives for litigation are much higher in

¹⁹¹ The mere “scintilla of utility” is a key term against which patent value is measured where no specific promise is made in the patent: “Where the [patent] specification does not promise a specific result, no particular level of utility is required; a ‘mere scintilla’ of utility will suffice” *Eli Lilly Canada Inc. v. Novopharm Limited* [2010] FCA 197, at 76, accessed February 20, 2015, <http://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/36863/index.do>.

¹⁹² These concepts are explored in substantial detail in Siebrasse 2014b and are key to his dispute with Gold and Shortt. To greatly simplify a complex argument, disclosure is the description of the invention. The ‘claims’ are what the patent promises an invention will do. True ‘promise doctrine’ cases involve a heightened utility standard for evidence used in description, where the patent in *New Process Screw (1961)* made a promise in the *claims* of the patent not simply in a description (Siebrasse 2014b, 7, 8). The problem with the promise doctrine is that evidence used simply to describe the invention (i.e. pre-clinical trials) is used to invalidate the patent when that evidence was not presented in the form of a specific claim of what the invention would do (i.e. a certain degree of clinical effectiveness).

Canada due to a lack of admissibility for post-patent proof in “sound-prediction” cases (Gold and Shortt 2014, 65).

Perhaps more importantly, Gold and Shortt’s assessment of TRIPS is consistent with the central component of this thesis related to the residual power of domestic institutions vis-à-vis international standards. They argue that “international agreements do not specify substantive patent content” and “TRIPS did not intend to legislate a global standard for patentable utility” (Gold and Shortt 2014, 58, 59). This is obviously part of an argument in support of dismissing a specific case,¹⁹³ but it also highlights an important limit to the international regime. International agreements only reach into domestic law to a certain extent. Many important details are determined domestically. By contrast, local entrenched judicial institutions have much closer proximity to the law and retain power over definitional interpretation.

Process Tracing the Historical Institutional Hypothesis

This section traces the relevant case law and illustrates how the path dependence of precedent supports the historical institutionalist (HI) hypothesis. The HI hypothesis for a narrowing of the broad TRIPS/NAFTA language is that historically rooted institutions and temporal sequencing have shaped this feedback response. For the HI hypothesis to be valid, we should see evidence of judicial capacity and that promise doctrine patent invalidations are explicitly linked to institutionalized standards.¹⁹⁴ Previous case law is instructive in this regard. We would also expect to see evidence of US pressure

¹⁹³ As discussed below, this relates to Eli Lilly’s NAFTA Chapter 11 Investor State Dispute Settlement case.

¹⁹⁴ For this to be verified using process tracing a smoking-gun test or doubly-decisive test would be required. In this case there is no doubly-decisive test available that could simultaneously rule-in the HI hypothesis and rule-out all other alternatives. As such, a smoking-gun test is applied here.

specifically addressing the promise doctrine and evidence of Canadian institutions resisting this pressure.¹⁹⁵ Indeed, no amount of US pressure to date has been able to challenge this entrenched institutional source of domestic power.

Citation of *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd. (1981)* is a good starting point as the definition of inutility in that case clearly conflicts with what was later articulated under TRIPS regarding commercial application. *Consolboard (1981)* cites Halsbury's Laws of England, (3rd ed.), vol. 29 where 'not useful' "means that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do... the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility."¹⁹⁶ This is at odds with the TRIPS definition of utility above that directly specifies commercial application. By adopting the *Consolboard (1981)* definition,¹⁹⁷ the court continues an institutionalized practice regarding utility that reaches back to English common law. It is not so much that the conception of utility is completely "new," but the *Wellcome (2002)* SCC judgment codified the approach in a specific legal standard for future use.

According to the Canadian Legal Information Institute (CANLII) database, 64 rulings jointly cite *Consolboard* (total 156) and *Wellcome* (total 131) as of March 2015.¹⁹⁸ Many rulings explicitly invoke the language in *Wellcome (2002)* and *Consolboard (1981)* to invalidate patents. However, qualitative analysis is needed as not all are invalidations or have led to a substantial material outcome. Some have been invalidated for multiple

¹⁹⁵ This element is examined in subsequent sections.

¹⁹⁶ *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* [1981] SCR 504, at 525, accessed February 27, 2015 <http://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2426/index.do>

¹⁹⁷ See for example, *Bristol-Myers Squibb v. Apotex*, [2005] FC 1348 *nefazodone*.

¹⁹⁸ CANLII database, accessed July 20, 2015, <https://www.canlii.org/en/>

reasons including lack of “sound prediction” or have been overturned on appeal.

In 2005, the Federal Court dismissed an appeal regarding evidence disclosure in *Bristol-Myers Squibb v. Apotex, (2005) FC nefazodone*. This case was not an invalidation but considered a clinically problematic pharmaceutical product that had just prior been removed from both the Canadian and the US market. This ruling, while relating to the disclosure of evidence, was among the first to jointly rely on *Consolboard* and *Wellcome* together to reassert the court’s interpretation of utility.

Also citing *Consolboard* and *Wellcome* was the 2005 PM(NOC) case *Pfizer Canada Inc. v. Canada (Minister of Health) (2005)* which did not uphold the patent for the product *quinapril*.¹⁹⁹ The judge agreed with the patent owner that “sound prediction” had been satisfied²⁰⁰ and that “double-patenting” was not at play.²⁰¹ However, under a reverse onus, the Federal Court found the patent holder had not proven that the patent did not make overly broad claims.²⁰² Specifically, the court held that the “claims of the ‘330 patent were broader than the invention disclosed.”²⁰³ The Federal Court of Appeal later reversed this decision in *Pfizer Canada Inc. v. Canada (Health), (2007) FCA 209 – quinapril*. Thus it should be noted that the standards and tests outlined in *Consolboard* and *Wellcome* do not always lead to invalidation, provided that ‘sound prediction’ is satisfied, and the court deems claims made about the patent’s use are not overly broad nor obvious.

¹⁹⁹ *Pfizer Canada Inc. v. Canada (Minister of Health)* [2005] FC 1205, at 12, accessed February 27, 2015 <http://www.canlii.org/en/ca/fct/doc/2005/2005fc1205/2005fc1205.html>

²⁰⁰ *Ibid* at 82.

²⁰¹ *Ibid* at 115.

²⁰² *Ibid* at 157.

²⁰³ As noted by the Federal Court of Appeal ruling. *Pfizer Canada Inc. v. Canada (Health)* [2007] FCA 209, accessed February 27, 2015 <http://www.canlii.org/en/ca/fca/doc/2007/2007fca209/2007fca209.html>.

Two important cases that also cite *Wellcome* and *Consolboard* involve the US corporation Eli Lilly and Company.²⁰⁴ These cases are central to the promise utility doctrine debate and were the basis of a NAFTA Chapter 11 Investor State Dispute Settlement (ISDS) case brought against Canada by the company. On the basis of the promise doctrine, Canadian courts ruled that Lilly's patents on the key products *olanzapine* and *atomoxetine* were not valid. After lengthy domestic litigation processes that were ultimately unsuccessful and a refusal by the Supreme Court to hear Lilly's case, the company launched an ISDS challenge in late 2012.

Lilly argued the promise doctrine imposes more onerous standards of proof in Canada that a patent will lead to a useful invention, even where there is a successful and clinically efficacious product on the market. Lilly claimed that this series of judicial rulings following *Wellcome (2002)* has put Canada offside of its NAFTA commitments and effectively expropriated its investments. It sought a government rectification or compensation of \$500 million. According to Lilly's second *Notice of Intent* filing:

By construing the "promise of the patent" as the standard against which utility is assessed, the Canadian Federal Courts are in effect requiring proof of the effectiveness of the compound in treating a disease or disorder at the date of filing of the patent application, which imposes a significantly higher onus on the patentee than the standard of credible or plausible utility that is mandated by the TRIPS Agreement and NAFTA...The measures in issue have had the effect of destroying the value associated with Lilly's investments, namely, the exclusive rights to prevent third parties from making, using or selling the patented product during the patent term and to enforce those rights.²⁰⁵

²⁰⁴ Exclusive of appeals, the two key cases are: 1) *Eli Lilly Canada Inc. v. Novopharm Limited*, [2007] FC 596 *olanzapine*, at 131, accessed March 20, 2015, <http://canlii.ca/t/1rqmk>; and 2) *Novopharm Limited v. Eli Lilly* [2010] FC 915 *atomoxetine*, at 91, accessed March 20, 2015, <http://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/58458/index.do>.

²⁰⁵ Eli Lilly and Company, "Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven," *Eli Lilly and Company v. of the Government of Canada* (June 13, 2013): 13, accessed August 11, 2013, <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/diff/diff/eli-02.pdf>. (an earlier notice of intent was initially filed on November 7, 2012.)

This statement formed the basis for Lilly’s claim that Canadian judicial rulings impose higher standards for patentability than found in TRIPS. In support of the notation that patent invalidations constitute an “expropriation” of the company’s investments, Lilly also argued that the standards were “radically new, arbitrary and discriminatory against pharmaceutical companies.”²⁰⁶

Prominent legal practitioners noted a “widely” held view that the doctrine is inconsistent with NAFTA obligations.²⁰⁷ In the view of others, the claim lacked basic credibility in that it used NAFTA’s investment Chapter 11 for an intellectual property matter. One interesting feature of the claim arises from the structure of ISDS. It holds the executive branch of government to account for judicial interpretations. The Government of Canada argued “in all but rare circumstances, a determination by a domestic court concerning the existence of a property right, including an intellectual property right, cannot amount to an ‘expropriation’ at international law.”²⁰⁸ Lilly noted that the rulings have been incorporated into the official Canadian Intellectual Property Office Practice

²⁰⁶ *Eli Lilly and Company v. of the Government of Canada* [2017] UNCT/14/2, Final Award, 1-2 at para 5, accessed April 6, 2017, http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf

²⁰⁷ “Canada is alone among developed nations in imposing these new utility requirements, which are widely considered to be inconsistent with Canada’s obligations under the North American Free Trade Agreement (“NAFTA”). Article 1709(1) of NAFTA states that a party (i.e. the Government of Canada) must grant a patent for inventions that are new, result from an inventive step (i.e. non-obvious), and are capable of industrial application (i.e. useful). Pursuant to NAFTA, Canada is not permitted to add further substantive conditions to the grant of patents.” Patrick E. Kierans, “USTR Slams Canada over the Treatment of Pharmaceutical Patents,” Norton Rose Pharma in Brief, May 2013, accessed December 10, 2013, <http://www.nortonrosefulbright.com/ca/en/knowledge/publications/79960>; Google cache: goo.gl/YPiBcY

²⁰⁸ Government of Canada, *Statement of Defense*, *Eli Lilly and Company v. of the Government of Canada*, (June 30, 2014) 1, 41, accessed July 20, 2014 <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-07.pdf>

Manual.²⁰⁹ An implicit point is that, as signatory to NAFTA, Canada has not taken legislative action to override the promise doctrine.

Past Decisions “Binding” Future Outcomes

This section briefly examines the long litigation history of the two key Eli Lilly cases. The text of the ruling in these PM(NOC) patent linkage proceedings show how past Supreme Court Decisions were “binding” on these outcomes. *Eli Lilly Canada Inc. v. Novopharm Limited*, (2007) FC 596 olanzapine was a PM(NOC) proceeding that first allowed a generic competitor on market. This case was preceded by a nearly identical testing of the same patent by Apotex which claimed the patent invalid on the basis of “anticipation,” “obviousness,” “double-patenting” and an “inferred” intention to mislead contrary to Section 53 of the *Patent Act*.²¹⁰ All of these allegations were dismissed and the court granted Lilly an order of prohibition against Apotex marketing a competitor. Following the Apotex ruling, a second case on the same product *Eli Lilly Canada Inc. v. Novopharm* included essentially an identical witness list and identical evidence as assessed by Justice Hughes J.²¹¹

²⁰⁹ Lilly clearly sees it as a state responsibility when arguing: “The Government of Canada is responsible under international law for the acts of the judiciary as an organ of the State. The Canadian Government and governmental bodies also caused the expropriation of the exclusive rights conferred by the ... patents by omitting to rectify the Judge-made law on utility and disclosure and by incorporating this Judge-made law into the practices of the Canadian Intellectual Property Office through the Manual of Patent Office Practices.” *Eli Lilly, Notice of Intent* [2013] supra, at 27.

²¹⁰ *Eli Lilly Canada Inc. v. Apotex Inc.*, [2007] FC 455, accessed March 20, 2015, <https://www.canlii.org/en/ca/fct/doc/2007/2007fc455/2007fc455.html>

²¹¹ Justice Hughes J. writes: “I am satisfied that the affidavits of the Lilly witnesses are essentially the same, and no material differences exist in respect of cross-examination. I am satisfied that the nature of the evidence given by the Apotex witnesses both by affidavit and in cross-examination is not materially different in any meaningful respect from that given by the Novopharm witnesses in the present proceeding.” *Eli Lilly Canada Inc. v. Novopharm Limited*, [2007] FC 596 at para 36, accessed March 20, 2015, <https://www.canlii.org/en/ca/fct/doc/2007/2007fc455/2007fc455.html>

Despite a clear consistency of evidence, this second round of litigation on the same molecule used the sound prediction test to invalidate the patent while leveraging the “disclosure as the public bargain” language from *Wellcome (2002)*. The second ruling upheld the earlier dismissal on the points of anticipation, obviousness, intention to mislead, and “double-patenting” (at 184, 185). However, the second decision also reflected the court’s aversion in principle to two periods of monopoly for selection patents, where those selections do not fulfill the institutionalized public bargain. As noted by the judge in that case, “Given that Lilly has already enjoyed a patent monopoly for a group of compounds that included olanzapine all said to be useful in treating [central nervous system] disorders, *it simply has not paid the price*, by way of a clear and explicit disclosure as to what the invention is” [emphasis added].²¹² Despite near identical evidence and near identical ruling on all other elements of validity, on the second go-around the patent was not held to be valid based on a lack of utility.

This approach by the generic sector to throw every potential argument for invalidity against the wall and “see what sticks” is common. The *Wellcome (2002)* utility test provides a powerful tool in this effort. The introduction of clear evidence of substantial commercial success explicitly had no bearing on the ruling.²¹³

Ironically, the judgment is significantly informed by English common law per *Halsbury’s Laws of England, (3rd ed.), vol. 29*, as cited in *Consolboard (1981)*. The English Court of Appeal itself upheld the validity of the exact same patent in *Dr. Reddy’s*

²¹² *Eli Lilly Canada Inc. v. Novopharm Limited* [2007] supra, at 164.

²¹³ *Ibid* at 187.

Laboratories (UK) Limited v. Eli Lilly and Company Ltd., (2009).²¹⁴ It appears that the Canadians are more faithful to the path laid out by English Law than are the English themselves.

Despite the objective of TRIPS and the PCT to harmonize patent standards internationally and create predictability for patent owners, patent utility is one area that has clearly not been harmonized in Canada's case. This creates international divergence on the same patents despite the same general issues and evidence. The Canadian Court was careful to safeguard autonomy from other international rulings in this regard.²¹⁵ In contrast, the English court in its conclusion of validity did "draw comfort" from a similar ruling affirming utility on this patent by the German Oberlandsgericht and on appeal by the Bundespatentgericht.²¹⁶

Every modern patent system is, of course, subject to judicial review and invalidation is always a possibility. However, the highly specific testing *criteria* on which this review is based in Canada is fairly new—more recent than many of the patent applications it impacts—and is wholly Canada-specific:

Canadian patents, especially in the pharmaceutical field, normally claim priority from a prior filing in the US or Europe, neither of which has a similar doctrine. Even Canadian patent drafters would not have been alert to this doctrine until recently. This means the patents that are being

²¹⁴ *Dr. Reddy's Laboratories (UK) Limited v. Eli Lilly and Company Ltd.*, [2009] England and Wales Court of Appeal Civ 1362 accessed March 28, 2015, <http://www.bailii.org/ew/cases/EWCA/Civ/2009/1362.html>

²¹⁵ Justice Hughes J. dismisses any consideration of the nearly identical adjudication of this patent with the *opposite* validity outcome by United States Court of Appeals for the Federal Circuit (CAFC) December 26, 2006, 471 F.3d 1369 and a US Supreme Court decision raised by the respondent: "I decline to enter into any consideration of these United States court decisions. While decisions of foreign courts, particularly superior and appellate courts of respected jurisdictions such as the United States are frequently instructive, it is not the function of this Court to consider whether an earlier decision of a foreign court would have been differently decided in view of a later decision of a higher court of that country. Nor should this Court consider as binding in any way a decision of a foreign court even if the patent and parties are similar and related although the decision may be instructive." *Eli Lilly Canada Inc. v. Novopharm Limited* [2007] *supra*, at 13.

²¹⁶ *Dr. Reddy's* [2009] *supra*, at 118.

invalidated in litigation today on the basis of the promise of the patent doctrine were drafted without regard to its requirements (Siebrasse 2013, 3).

This practice impacts predictability for patent owners and complicates the regime goal regarding international convergence of expectations. In summary, Canada is an outlier among common legal systems.

The second case *Novopharm Limited v. Eli Lilly (2010) FC 915 atomoxetine* again highlights that commercial utility has little force in Canadian patent adjudication. Perhaps learning from its experience in the olanzapine case, Lilly's counsel conceded the point on commercial application: "[Counsel] is correct when he argues that utility does not mean commercial usefulness."²¹⁷ Interestingly, for the same product Lilly pursues a very different line of argument in its NAFTA investor state dispute settlement (ISDS) complaint where it takes great pains to stress the commercial utility and success of its product. This was part of Lilly's expropriation claim and the supporting argument that Canada had broken with historical practice, where previously, no commercially successful products were found to lack utility.²¹⁸

One key argument made by Lilly is that the heightened standard of utility is not reflected anywhere in the *Patent Act*. At the time of its patent application in 1996 the tests set out in *Wellcome (2002)* could not have been foreseen. In a crucial passage, the trial judge defers on this point citing the Canadian institutional standard he must work within:

Lilly argues that the validity of the '735 Patent is now being assessed against the backdrop of a more rigorous disclosure obligation than may have been apparent at the time of its filing in 1996. Lilly also questions

²¹⁷ *Novopharm Limited v. Eli Lilly* [2010] supra, at 112.

²¹⁸ In response, the tribunal noted the following: "Tribunal accepts Claimant's point that before AZT, no commercially successful products were found to lack utility, whereas now this is not uncommon. This is a notable fact, but Claimant has not established this to be the result of changed law" *Eli Lilly v. Canada* [2017] supra, at 104 para 336.

what public policy or statutory purpose is served by imposing a heightened disclosure obligation in cases of a sound prediction of utility – provided, of course, that what is disclosed is sufficient to understand and to work the invention. The *disclosure issue, however, has been determined by earlier decisions that are binding upon me* and to the extent that it may be amenable to reconsideration, it must be examined elsewhere [citation omitted, emphasis added].²¹⁹

It is hard to imagine a smoking-gun statement that more aptly supports the historical institutional hypothesis. The judge clearly does not see an option other than striking down the patent on the basis of inutility as identified by the sound prediction test in *Wellcome (2002)*.

Some of the normative language from *Wellcome* identified above is reproduced in *Novopharm Limited v. Eli Lilly (2010) atomoxetine*.²²⁰ This is reflected in somewhat more of a utilitarian style: “sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly.”²²¹ The idea of a *quid pro quo* between inventor and “the Crown, representing the public” regarding description of the invention has an institutionalized history and is also cited in *Consolboard (1981)*.²²² This standard and the invocation of the public bargain regarding disclosure also seems to suggest that norms and judicial identities as defenders of that bargain also play some role. In this case, we do not need to go down the winding road of mutual constitution of agents and structures to see some validity in a constructivist-informed hypothesis. While the HI smoking-gun test is satisfied, it is not a double-decisive test, and there is room to consider equifinality by viewing this judicial development through a pluralist lens. In this case, both norms and institutions contribute to explaining the outcome. Historical sequencing is

²¹⁹ Ibid at 121.

²²⁰ Note this case did not involve a selection patent.

²²¹ *Wellcome* [2002] supra, at 70; *Novopharm v. Eli Lilly* [2010] supra, at 92, 117.

²²² *Consolboard* [1981] supra, at 517.

also relevant as previous decisions create institutionalized practices that clearly bind future outcomes.

Scope and Impact

There are several other cases that leverage and contribute to this case law. This section continues to process trace the promise doctrine's scope and impact. While the full impact is inherently difficult to assess, there can be no doubt that the case law provides a significant constraint on patentability in Canada.

Lilly's *Notice of Intent* points to a substantial increase in generic company attempts to invalidate patents sector-wide following "promise doctrine" case law that began around 2005. According to Lilly, in the 25 years prior (1980-2005) there were only 33 patent-utility challenges in Canada, two of which led to successful patent invalidations. In just 7 years following 2005, (2005-2012) Canadian courts apparently heard 58 utility challenges and 19 invalidations, all of which were related to pharmaceutical patents.²²³ These figures were not individually specified by Lilly but were identified by both Lilly's and Canada's expert witnesses during the ISDS arbitration.

A chronology of key cases and appeals is included in ANNEX C, listed by date of first proceeding. This list was extracted from the expert witness report of Dr. Bruce Levin, a Columbia University biostatistician and Lilly witness in the ISDS arbitration. The analysis has been updated to reflect some critiques and refinements made by Canada's expert witnesses. A few more recent cases have also been added. The list rightly includes PM(NOC) cases which are summary judgments and not technically patent 'invalidations.' As discussed herein, these cases have real-world impact and

²²³ Eli Lilly, *Notice of Intent* 2013 supra, at 14.

importance and cannot be excluded.²²⁴

Another case that deserves particular mention is the long saga of litigation on blockbuster drug Plavix. Litigation on the molecule was granted leave to the Supreme Court twice before it was settled out of court on the eve of its second Supreme Court hearing.²²⁵ Initial claims of “anticipation, obviousness and double patenting” were dismissed in the first round of litigation. The patent returned to the SCC the second time on basis of the promise doctrine. In its 2014 factum, the drug’s manufacturer Sanofi argued that Canada’s subsequent interpretation of *Consolboard (1981)* has taken the

²²⁴ The Government of Canada argued that PM(NOC) cases should be excluded from Levin’s statistical analysis due to the summary nature of those proceedings. This position is tenuous given the clear importance of the PM(NOC) process. Canada’s witness statement from government policy analyst Marcel Brisebois notes that “unlike in an impeachment or infringement decision in which a patent is declared invalid in whole or in part, a PM(NOC) decision does not declare the challenged patent invalid. It remains valid, and can be asserted in subsequent PM(NOC) infringement or impeachment proceedings.” Arguably, this is not true in the case of PM(NOC) given that an earlier PM(NOC) loss can form the basis for a summary dismissal as an abuse of process (see Chapter 4 above). Furthermore, a PM(NOC) loss impacts real-world market exclusivity, allowing the marketing approval of a competitor which is a substantial curtailment of a patent owners IP rights. The cases are also important sources of judicial precedent. The debate within the Lilly ISDS arbitration on which cases to include relates to statistical significance of pre- and post-2005 utility-based pharmaceutical patent invalidations as compared to invalidations in other business sectors. While Lilly’s witness is correct to have included PM(NOC) cases, his finding of statistical significance is not necessary to establish the institutional outcome of a narrowed definition of utility. The fact that since *Wellcome (2002)* there have been 24 pharmaceutical patents found invalid on utility grounds as compared to none pre-Wellcome, and none post-2005 in other business sectors is an obvious indicator (see Annex). Additionally, the increase in total pharmaceutical utility-based litigation obfuscates the issue. Between 1980 and 2005 pharmaceutical cases comprised only 3 of 27 total utility-based challenges and none of those three were found invalid. Post-Wellcome, the incentives for challenges were greatly increased due to case law and fully 63 of 69 utility-based challenges were pharmaceutical cases (see Annex). No patents in other sectors were actually invalidated in this period on grounds of utility. Bruce Levin, “Expert Report of Bruce Levin, Ph.D; Professor of Biostatistics, Columbia University” September 7, 2015 Case No. UNCT/14/2, accessed August 2, 2016, <http://www.italaw.com/sites/default/files/case-documents/italaw4376.pdf>; Marcel Brisebois, “Second Witness Statement of Marcel Brisebois” December 7, 2015, Case No. UNCT/14/2, accessed August 2, 2016, https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC7237_En&caseId=C3544

²²⁵ *Apotex v. Sanofi-Synthelabo Canada* [2008] SCC 61 File No. 31881 accessed March 10, 2015, <http://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2575/index.do>; *Apotex v. Sanofi- Aventis Canada* [2014] SCC File No. 35562 accessed March 10, 2015, <http://www.scc-csc.gc.ca/case-dossier/info/dock-regi-eng.aspx?cas=35562>

promise doctrine well beyond its UK origins and well beyond the Canadian *Patent Act*.²²⁶ Sanofi noted that *Consolboard (1981)* cites pre-1977 UK law. At this time there was a UK statutory measure for invalidity based on a “false promise” *on fact* (i.e. not on sound prediction of utility as of the patent filing date per Canada).²²⁷ Since 1977 the UK has moved via legislation to an ‘industrial application’ of utility. A similar approach was subsequently adopted in TRIPS:

Since 1977, the UK Patents Act has not contained this statutory ground of invalidity. Thus, patents can no longer be held invalid on the basis of a false promise or suggestion. UK patents however still must have some utility, which is measured on whether it is ‘plausible’ that the invention is capable of industrial application, a very low threshold.²²⁸

This further demonstrates the salience of historical institutionalism. The UK moved to an industrial application threshold in law. It made a clean break with history in advance of TRIPS. Yet the legacy of its past standards significantly impacted the evolution of Canadian case law. The promise doctrine would not have become such an important international issue had Canada implemented TRIPS differently and modified its *Patent Act* to more closely reflect the language of industrial application.

Estimates for the financial magnitude of the promise utility doctrine are still nascent, often shrouded in secrecy due to legal strategy, and none have been validated by academic peer-review. Eli Lilly claims \$500 million for Canadian patent invalidations of two of its major products noted above. An opt-ed penned by a former United States Trade Representative (USTR) staff has claimed \$1.1 billion and 23 patents “revoked” without

²²⁶ Sanofi-Aventis Canada et al., Factum of the Respondents in *Apotex v. Sanofi- Aventis Canada* [2014] SCC File No. 35562 at 70, 72-77, accessed March 10, 2015 http://www.scc-csc.gc.ca/WebDocuments-DocumentsWeb/35562/FM030_Respondents_Sanofi-Aventis-et-al.pdf.

²²⁷ Ibid at 67, 70.

²²⁸ Ibid at 71.

citation or sourcing of this estimate.²²⁹ US pharmaceutical industry associations in their representations to the USTR have only provided specific estimates for *US-owned* patents and have claimed a conservative *minimum* of \$750 million in *direct* damages for around 20 patents invalidated by Canadian courts under the promise utility doctrine (BIO 2015, 20; CPUC 2015, 7). These estimates used *IMS Health* sales data but are non-transparently disclosed with confidential data redacted. The associations' claim is that sales losses are more accurately in the billions when the full range of impacts is accounted for. These include "additional damages paid to competitors as a result of Canadian decisions applying the promise doctrine," patent application denials by the Canadian Intellectual Property Office (CIPO), pending trials, and "forfeiture of intellectual property rights granted in similarly-situated economies around the world" (CPUC 2015, 7).

The impacts on the Canadian market are not unsubstantial. Even a conservatively assumed \$1.3 billion impact estimate would constitute approximately 10% of the annual \$13.6 billion output of the entire patented pharmaceutical industry in Canada (PMPRB 2014, 15).²³⁰ Perhaps a greater concern for patent owners is the perceived threat to similar invalidations in other international markets. The US does not want to see other major markets experiment with more onerous tests for utility and undermine its TRIPS accomplishments. One indicator of the concern is that US industry has supplemented its traditional association advocacy via The Pharmaceutical Research and Manufacturers of America (PhRMA), Biotechnology Innovation Organization (BIO), and the US Chamber

²²⁹ Michelle Wein, "Canada's False Patent Promise" *National Post* Comment: March 17, 2015 accessed March 28, 2015, <http://news.nationalpost.com/full-comment/michelle-wein-canadas-false-patent-promise>

²³⁰ Figure for 2013.

of Commerce Global Intellectual Property Center (GIPC) by setting up an issue-specific association, the “Canadian Patent Utility Coalition” (CPUC).

There are many barriers to constructing a reliable financial impact assessment of the promise utility doctrine. Companies do not want any company-specific data disclosed due to shareholder concerns and the risk of spreading an international “contagion”²³¹ of invalidations for their patents. Furthermore, there is no way to quantify the impact for cases that are settled for undisclosed sums. This was the case for what was to be a landmark Supreme Court ruling on the promise doctrine that was settled out of court the day before its hearing.²³² The issue of non-transparent settlements between brand and generic companies has raised eyebrows from competition regulators in both Canada and the US, particularly those settlements that might lead to an anticompetitive “pay-for-delay,”²³³ where “brand drug companies [pay] generics to drop patent challenges and delay entering the market” (Competition Bureau 2014, 2). Another point of uncertainty is the counterfactual for the products that did not apply or were not granted a patent under the heightened standard.

²³¹ Michelle Wein, “Canada’s False Patent Promise” *National Post*, March 17, 2015.

²³² Apotex Inc., et al. v. Sanofi-Aventis, et al. [2014] Supreme Court of Canada, Docket 35562, accessed February 20, 2015, <http://www.scc-csc.gc.ca/case-dossier/info/dock-regi-eng.aspx?cas=35562>

²³³ Competition regulators in the US are starting to get a handle on the magnitude of these issues through a notification system and the US administration has proposed a prohibition on so called pay-for-delay settlements. The 2016 US Department of Health and Human Services (HHS) Budget outlined the US Administration’s plans to empower the Federal Trade Commission to “prohibit anticompetitive pay-for-delay agreements” and block brand and generic drug manufacturers from entering into settlements that could delay generic entry. These prohibitions are estimated to save Government Insurance plans Medicare and Medicaid around \$10 billion over 10 years (HHS *Fiscal Year 2016: Budget in Brief* 2015, 71). In Canada, the Competition Bureau is following the US’s lead by identifying potential issues in the Canadian context and calling for a public notification system similar to that in the US (Competition Bureau 2014). The Competition Bureau has also taken steps to update its Enforcement Guidelines for Intellectual Property to clarify its interpretation of settlements under the Patented Medicines (Notice of Compliance) Regulations. Competition Bureau, *Intellectual Property Enforcement Guideline, Draft for Consultation*, June 9, 2015, accessed June 10, 2015, http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03935.html#section7_2

Despite the challenges, precision on the specific financial impact is not required for the purposes here. US research suggests that one year following generic competition, brand market share typically erodes to only 16% of sales (by unit) (Grabowski, Long, and Mortimer 2013, 1). For large products, defined by US sales in excess of \$250 million USD, the erosion is even greater to just 11% of the former market (Ibid). Given the incentive structure for generic pharmaceutical companies to pursue cases, it is perhaps not surprising that these invalidated patents relate to some of the most lucrative (or potentially lucrative) products on the market. There can be no doubt that the invalidation of these high revenue products constitutes a meaningful constraint on the TRIPS standards both at the individual product level and at the national system level. More fundamental than the direct financial impacts felt by industry is the political outcome and policy implication of an assertive federal judiciary.

Ultimately, the arbitration panel sided with Canada's view, dismissed Lilly's claim and awarded legal costs to Canada.²³⁴ This outcome is fully consistent with the present theory and supports the fact Canada maintained considerable domestic sovereignty under NAFTA. The power of domestic courts to interpret patent utility remains fully intact. As it turns out, reports of the death of Canadian sovereignty were greatly exaggerated. The tribunal noted that under the circumstances of a rational and non-arbitrary policy approach "it is not the role of a NAFTA Chapter Eleven tribunal to

²³⁴ The case hinged on the views of three international commercial law arbitrators from the UK and the Netherlands: Professor Albert Jan van den Berg, Mr. Gary Born, and Sir Daniel Bethlehem. The Tribunal found that the invalidations could not "form the basis of an expropriation claim under NAFTA Article 1110 or a claim for a violation of the minimum standard of treatment under NAFTA Article 1105." *Eli Lilly and Company v. Government of Canada* [2017] UNCT/14/2, Final Award, 146 at para 469, accessed April 6, 2017, http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf

question the policy choices of a NAFTA Party.”²³⁵ The tribunal rejected the notion that the promise doctrine constituted “a dramatic change in law” noting that it reflected a “more incremental and evolutionary” change. This is an important distinction when considering whether Canada ‘expropriated’ investments or simply applied the law according to the constraints of past precedent.²³⁶

This is not the end of the promise doctrine saga. The Supreme Court of Canada will rule on an additional case in 2017 that could provide further clarity on this issue. There are also potential international implications. According to Gold, the tribunal decision “[sends] a signal that countries can phrase their patent laws in a way that suits their national needs.”²³⁷ Alternatively, PhRMA notes:

the tribunal did not need to consider the inconsistency of Canada’s patent utility doctrine with its international obligations... [the] Canadian Government has a choice. Through a quick legislative fix, Canadian courts would be required to live up to global standards of patentability, which purposely set a low bar for demonstrating utility. This is the same standard implemented in the United States, Europe and Japan.²³⁸

US promise doctrine advocacy will clearly continue. It is a likely US target for the 2017 NAFTA renegotiation.

In summary, Canadian courts have articulated a national standard for patentable utility that is wholly Canada-specific and there is ongoing disagreement on its compliance with international regime standards. A NAFTA Chapter 11 dispute settlement process designed to hear investment expropriation claims and not intellectual property

²³⁵ *Eli Lilly v. Canada* [2017] supra, at 146 para 426.

²³⁶ *Ibid* at 100, 108.

²³⁷ Paul Webster, “Canada wins legal battle to set patent rules” *CMAJNews* March 28, 2017, accessed April 4, 2017, <http://cmajnews.com/2017/03/28/canada-wins-legal-battle-to-set-patent-rules-cmaj-109-5168/>

²³⁸ Mark Grayson, “NAFTA tribunal fails to rule on Canada’s patent utility doctrine” April 4, 2017, accessed April 5, 2017, <http://catalyst.phrma.org/nafta-tribunal-fails-to-rule-on-canadas-patent-utility-doctrine>

matters was an unconventional vehicle to address concerns regarding the appropriateness of Canada's patent utility regime. Through this process, path dependent judicial standards have remained resilient. Canada's narrow and path dependent implementation of NAFTA and TRIPS²³⁹—which did not replace existing Canadian standards with an “industrial application” standard—has survived for the time being. Regardless of this outcome, there can be no doubt that this case has helped to undermine the public legitimacy of ISDS. This is a tricky for Canada because dispute settlement is a key institutional protection in managing power asymmetry with the US and was a central NAFTA accomplishment (see ANNEX B).

US Pressure and the Canadian Response

This section turns to the second part of the historical institutionalism test identified above. For historical institutionalism to provide an alternative to market power we should see clear evidence of US pressure and Canadian officials relying on institutions to push back. This section helps to show that despite considerable pressure from the US, Canadian institutions are resilient. Furthermore, this section shows that the causal mechanisms previously identified in the HI literature could be strengthened via research design to better support the approach (Sell 2010). “Naming and shaming” of Canada by the US Trade Representative has not been effective in this case. Naming and shaming is only one of several mechanisms of policy diffusion.²⁴⁰ It is a tactic, and is arguably not that central to the core historical institutionalism theory as are other elements of Sell's argument, namely, the institutionalization of the office of the USTR. However, as argued

²³⁹ Note that the Tribunal only considered NAFTA given its mandate for Chapter 11 disputes.

²⁴⁰ Furthermore, it is difficult to distinguish this from a market power approach when pursued by the US.

herein, Canadian *resistance* to naming and shaming from its most important and most powerful trading partner *does* support an HI hypothesis by illustrating how domestic institutions counteract international power.

While it may seem to be an arcane point of patent law, the issue of technological utility is an important bilateral issue. It is seen by the US as undermining the Canadian patent system and US claims to control of technology. It is important for the US because Canada is a sizable market for technological goods and also because of its symbolic value in other markets. The USTR's Special 301 list is an annual publication reporting on the "adequacy and effectiveness of US trading partners' protection and enforcement of intellectual property rights and market access for persons that rely on [IP] protection"²⁴¹ It is a primary advocacy tool and source of moral suasion for pressuring countries on IP. On its own, the 301 report is simply an IP score-card and only triggers the US to seek remedies for what the USTR sees as the most egregious challenges to US corporate interests. The list is determined by the USTR in consultation with impacted stakeholders, foreign governments, Congress, and is influenced by other interested parties. Notably, the Pharmaceutical Research and Manufacturers of America (PhRMA) submit positions annually based on its member company interests. Many of these positions are directly reflected in the USTR's final report.

The Special 301 report divides countries into three designations: 1) "watch list", 2) "priority watch list", and 3) "priority foreign country" with only the latter potentially subject to an investigation under the Section 301 provisions of the US *Trade Act* of 1974. This designation is reserved for only the most aggressive violations of IP and designation

²⁴¹ US Trade Representative "USTR Releases Annual Special 301 Report on Intellectual Property Rights," May 1, 2015, accessed March 12, 2015 <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2013/may/ustr-releases-annual-special-301-report>

is rare—one country in the seven years prior to 2013. For most designations, the list does not have practical legal implications beyond its utility as a naming and shaming²⁴² tool to pressure governments to make IP reforms, improve enforcement, and as a reminder of commitments made under international trade and investment agreements.

The USTR has kept Canada, its close ally and neighbor, on the 301 List for over a decade. PhRMA makes a detailed submission to the USTR every year in advance of the 301 report and requested Canada keep its “priority watch list” designation in 2013-2015 due to what it sees as: 1) weak enforcement of patents; 2) utility requirements inconsistent with the Canadian *Patent Act*, TRIPS and NAFTA commitments and “international norms;” 3) limitations on regulatory data protection; and 4) a lack of patent term restoration when regulatory approval or other delays diminish effective patent life (PhRMA 2013; 2014). In May 2013, despite PhRMA’s advocacy Canada received a minor upgrade from the Priority Watch List (held since 2009) to the Watch List “in recognition of significant progress on copyright issues.” This upgrade reflects non-pharmaceutical-related IP enhancements following Canada’s passage of the *Copyright Modernization Act* in 2012.

The issue of promise utility doctrine invalidations kept Canada on the 2013 USTR Special 301 List, which is highly critical of the Canadian regime.²⁴³ Similarly, the issue of “heightened utility requirements” surfaces in the 2014 USTR report although with considerably more specificity on the issue:

²⁴² This terminology from Sell (2010) see definitions above.

²⁴³ With respect to pharmaceuticals, the United States continues to have serious concerns about the availability of rights of appeal in Canada’s administrative process for reviewing regulatory approval of pharmaceutical products and also has serious concerns about the impact of the heightened utility requirements for patents that Canadian courts have been adopting recently. The United States looks forward to continuing its close cooperation with Canada on [IP rights] issues, including through the [Trans-Pacific Partnership] negotiations (USTR 2013, 46).

The United States also has serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently. Under this amorphous and evolving standard, courts can invalidate a patent on utility grounds by construing the "promise of a patent" years after the patent has been granted, leading to uncertainty for patent holders and applicants and undermining incentives for investment in the pharmaceutical sector. In applying this standard, courts have invalidated a number of patents held by U.S. pharmaceutical companies, finding now that those products lack utility (i.e., not capable of industrial application), even though such products have been in the market and benefiting patients for years. The United States will closely monitor developments on these issues and looks forward to continuing to work with Canada to address these and other IPR issues, including through the TPP negotiations (USTR 2014, 49).

This statement is perhaps unsurprisingly symmetrical to PhRMA's 2014 301 submission to the USTR (PhRMA 2014, 75-81). PhRMA's 2015 submission contains essentially the same positioning, but with more support in the form of cases cited, many of which are also considered herein (PhRMA 2015, 82). PhRMA has declined to date to provide a cost estimate (Ibid, 88).

The USTR statement is most interesting for its parenthetical use of "industrial application," a direct utilization of the broad TRIPS language on patentable utility (see TRIPS definition above, this chapter). The use of parentheses confuses the issue somewhat given that no product has been invalidated in Canada for not being commercially viable, but rather for lack of sound prediction, obviousness, or a number of other evidentiary reasons cited above. In fact, it is the *lack of consideration* of evidence of commercial success that *creates* the problem for US patent owners (Ibid). This is a regime design and implementation issue reflecting TRIPS' failure to modify institutionalized practice to replicate key language in Canada's *Patent Act*.

PhRMA maintains that the judicial action and the promise doctrine are actually inconsistent with the *Patent Act*, however, this is not likely supportable. It is not the case

that the court does not recognize that these products have industrial application, but rather the court feels that it cannot take this into account because of past decisions and the doctrine of precedent. The promise utility doctrine is in some ways the court's alternative to the industrial application standard under TRIPS. As of 2017, this approach was winning the day due to the court's authority and proximity to the practical application of Canadian law. It is also an assertion of the court's authority and independence from US approaches and decisions.²⁴⁴ This type of nuance would not be possible to capture under a market power approach which cannot be truly sensitive to within-state dynamics.

Internal government of Canada ministerial memos and lines for media engagement obtained under the *Access to Information Act* suggest that Canada easily dismisses US concerns:

In the 2016 [Special 301] Report, U.S. industry stakeholders continue to raise concerns with Canada's requirements for patent utility, citing industry allegations concerning the invalidation of patents on this basis by the Canadian courts...Canada considers the Special 301 process and the Report to be invalid and analytically flawed because the process relies primarily on U.S. industry allegations rather than empirical evidence and objective analysis...Canada does not recognize the validity of the Special 301 [report]²⁴⁵

Canada's dismissal and blasé outlook on USTR naming and shaming would seem to be partially linked to a lack of uptake by Canadian media: "As usual, the Report has not garnered significant attention in Canadian media."²⁴⁶

In addition to USTR pressure, the US pursues bilateral advocacy on IP and patent utility through traditional bilateral channels. In late 2013, the US Senate considered

²⁴⁴ *Eli Lilly Canada Inc. v. Novopharm Limited* [2007] supra at 13.

²⁴⁵ Global Affairs Canada, Media Lines "2016 USTR Special 301 Report on Intellectual Property Rights" May 10, 2016.

²⁴⁶ Graham Flack, Deputy Minister Canadian Heritage, Information Note for the Honourable Melanie Joly, May 10, 2016

Bruce Heyman as President Obama's nominee for Ambassador to Canada. The questions posed by the Chairman of the Foreign Relations Committee, Democrat from New Jersey Robert Menedez, reveal interesting insights on foreign policy priorities related to Canada. This question and its response from eventual plenipotentiary Heyman reflect the priorities of the administration. The passage also reflects the priorities Menedez' major corporate constituents, the New Jersey pharmaceutical industry, where many multinationals' head offices are located.

Chairman Menedez:

We have pushed for strong IP protections in the TPP agreement, Canada has not, and to date, has not been supportive of pro-innovation efforts in those negotiations or in its own domestic practices. An example can be found in the heightened standard for patentable utility that Canada now uses which is contrary to the global best practices and its international commitments. That innovators should face significant intellectual property challenges with one of the largest trading partners with the United States is a serious concern, so if you are confirmed what steps would you take to address Canada's access barriers...with respect to IP protections through the TPP, and otherwise?²⁴⁷

In response, Bruce Heyman:

...Intellectual property rights are the core of what American institutions depend on to compete globally. American ingenuity is our special sauce, and we work so hard doing research and development at the corporate level and depend upon patent rights and protections when we sell products overseas. I am aware of the issues that have been brought up with respect to intellectual property rights...if considered to be Ambassador by this esteemed committee, I will take this issue to the Canadian government, and I will make this issue an important issue... my number one mission [will be] expanding our economic footprint, but unless we have the intellectual property protections for our companies, it will make it incredibly difficult to expand those relationships... so I will make that a priority.²⁴⁸

The passage is important because it highlights the failure of TRIPS/NAFTA—cited as

²⁴⁷ Robert Menedez (D-NJ), Question Posed to Bruce Heyman, *US Senate Committee on Foreign Relations*, Washington D.C. December 11, 2013.

²⁴⁸ Bruce A. Heyman, testimony at Senate Nomination hearing regarding US Ambassador to Canada, US Senate Committee on Foreign Relations Washington, DC. December 11, 2013.

Canada's "international commitments"—to sufficiently shape domestic institutional processes and the determination of patent utility. It is interesting that US lawmakers express concern over Canadian domestic IP practices in the context of the size of the Canada-US trade relationship. The passage also shows how domestic reforms are then linked to future trade agreements like the Trans-Pacific Partnership.

From the US perspective, the issue of patent utility and judicial patent invalidation establishes an important international precedent. This poses a threat to all of the IP-related economic statecraft the US has engaged in over the past several decades. If the US cannot protect its IP-related commercial interest with its closest neighbor, major trading partner, security dependent, and cultural companion with highly similar judicial institutions, then what hope does it have elsewhere? Given all of the other important Canada-US issues at play,²⁴⁹ the fact that IP and the promise doctrine play such a significant role in bilateral relations is a telling indicator of its priority.

Beyond parochial corporate interests, the broader US business model relies heavily on building institutional protections for its knowledge and service-sector assets. Trade deals are important to diffusing governance norms and securing IP commitments. However, these commitments mean little if they are undermined by subnational administrative processes. While the invalidation of a handful of Canadian patents and a couple billion in lost revenue is not a major issue for the US from a structural perspective, the threat of *superficial or easily revoked* IP commitments clearly is.

In its legal defense of the Eli Lilly case, Canada explicitly defended judicial

²⁴⁹ Notable examples include: the Keystone XL pipeline, Beyond the Border Initiative, Regulatory Cooperation Council, Arctic sovereignty and defense, *Foreign Account Tax Compliance Act* implementation, intelligence collaboration, Buy-America procurement, and wind-up of Afghanistan mission.

practices with respect to patent invalidation and the two-step patent office and judicial review process. Canadian government lawyers' *Statement of Defense* downplays the inherent value of Canadian patents that have not yet been subject to judicial review, positioning them as simply "administrative":

Unlike the initial administrative reviews by the Patent Office, which rely on the patent specification as filed and assumptions in favour of the applicant, the Federal Court will review a patent's validity in light of extensive expert and fact evidence, presented in an adversarial court process between private parties...

Claimant was well aware that initial patent grants...were only presumptively valid...It was also aware that for its patents to remain valid they would need to withstand not only the Patent Office's administrative review, but rigorous court scrutiny, in an adversarial process.²⁵⁰

This legal positioning illustrates how the administrative bifurcation between a relatively weak federal patent office whose "decisions" are routinely overruled by a relatively strong Federal Court system can have a meaningful impact on outcomes. This is similar in many other national patent systems. The multisite diffusion of authority at the national level helps to produce cross-national variation in patent interpretation.

In general, when considering intellectual property Canadian officials seem to recognize their autonomy regardless of pressure from trading partners. For example, internal Canadian government briefing materials obtained under the *Access to Information Act* suggest IP modernization in the CETA context was focused on meeting basic international commitments while accommodating domestic realities:

Internationally, Canada has faced pressure to align its IP framework with international standards...[Despite] meeting international treaty obligations, there remain calls for further improvements, mainly stemming from perceived divergences from policies adopted by the United States and the European Union... Stakeholders are often

²⁵⁰ Government of Canada, Statement of Defense, *Eli Lilly v. Canada* (2014) at 20; 39.

polarized, especially in copyright and pharmaceuticals... Key drivers affecting Canada's IP include: International pressure – the US and EU have criticized Canada for lagging behind on IP policies. Trade agreements and IP treaties including TPP and CETA have been very important accelerators of IP reforms for Canada in recent years... Despite economic pressure, Canada's IP laws need to align with the domestic context.²⁵¹

While it is not entirely clear from this heavily redacted memo to what specific domestic context the official is referring, it must either be the domestic legal context or the domestic political context. Either supports a hypothesis that existing domestic institutions matter (in addition to power factors as reflected in the statements on US and EU pressure).

In summary, this section has argued that Canadian judicial institutions have proved to be powerful and resilient. At the international level, Canada operates under tremendous power asymmetry with the US. There has been substantial pressure to amend the promise utility doctrine via bilateral diplomacy, 'naming and shaming' via the USTR Special 301 watch list, and under a NAFTA Chapter 11 Investor State Dispute Settlement (ISDS) case brought by the US manufacturer Eli Lilly. To date, however, Canada has resisted this pressure relying on the argument that TRIPS/NAFTA in no way constituted an abdication of domestic courts to determine patent validity.²⁵² Canada has deferred to the authority of the judicial branch on this matter and not taken any legislative action to override the promise doctrine under pressure from the US. The strategy is effective because Canada-US power asymmetry is far less relevant at the institutional level than in a trade context. This type of within-state nuance cannot be captured in dominant market

²⁵¹ John Knubley, Deputy Minister, Innovation, Science and Economic Development, Advice to the Minister of Innovation, Science and Economic Development – Secret – CCM287598 "Canada's Intellectual Property Framework," April 20, 2016

²⁵² Government of Canada, Statement of Defense, *Eli Lilly v. Canada* (2014) 10, 86, 89.

power accounts in IPE. Institutional power clearly matters even when it may be at odds with regulatory objectives underwritten by US market power.

Taking Equifinality Seriously

It is useful to consider some alternative hypotheses.²⁵³ This section considers Canadian standards under the lens of neorealism, neoliberalism, and constructivism. It argues that realist and neoliberal alternative hypotheses are not instructive but constructivism cannot be dismissed. As such, a pluralist approach that considers historical institutionalism in combination with other approaches is most productive.

In the case of the promise doctrine, the neorealist or “market power” alternative hypotheses for the outcome is clearly not determinative. If market power explained the outcome of a narrowing definition of patentable subject matter, then the US should have favored this outcome. As discussed in the preceding section, this is clearly not the case. The US has been quite active in opposing this evolving Canadian standard and US multinationals have expended countless legal resources in this effort. Furthermore, a neorealist approach is not generally aligned with opening the black box of the state.

The neoliberal hypothesis in this case relates to cooperation and utility maximization. For example, one could argue that in order to facilitate cooperation and secure agreement on TRIPS/NAFTA its language had to be weak in defining utility. In this scenario, the US effectively bears the costs of cooperation through standards that are vulnerable to local challenge leading to only partial enforcement of its patents, and thus

²⁵³ Stop criteria for process tracing is usefully established on a deductive basis. By establishing tests in advance that, once met or failed, inform the validity of the hypothesis analysts can set the parameters without arbitrarily picking a time or level of detail to stop process tracing. For example, the failure of a hoop test, which must be passed for the hypothesis to be valid, would indicate a stop is warranted and the hypothesis nullified. As such, hoop tests are most useful for examining and dismissing alternative hypotheses (Bennett and Checkel 2014, 17).

the most utility-maximizing solution to facilitate agreement. In order for this hypothesis to be valid, there should be evidence that negotiators *realized* this compromise as part of negotiations. However, even if negotiators did consciously reach a compromise on this point, it never might have been made explicit and this would be tough to confirm. Documentation regarding trade negotiations is often scarce. In cases of scarce evidence, hoop tests can sometimes provide highly probable insights despite limited data.

A relevant hoop test for the neoliberal hypothesis—what categorically must be true if neoliberalism explains the narrowing of patent scope—would be evidence that the TRIPS/NAFTA language permitting the promise doctrine was an intended concession to Canada as the regime-taker. To better contextualize Gold and Short’s assertion that TRIPS never intended “to legislate a global standard for patentable utility,” the US very much did intend that US multinationals’ patents would be upheld based on TRIPS’ extremely broad and encompassing definition of utility.²⁵⁴ In theory, it could be interpreted to essentially exclude no commercially marketed product. The key point is that TRIPS language on utility (“may be deemed by a member”) provided sufficient scope for domestic interpretation. Canadian courts have clearly *not* adopted the very broad international definition of utility as “capable of industrial application” but rather have narrowed it through heightened disclosure requirements. The courts have done so partially through *Wellcome (2002)* by excluding from admissibility the core type of evidence that can conclusively establish capability for industrial application: evidence obtained following the patent date including evidence of commercial success.

The classic example of a hoop test provided in the process tracing literature is summarized as follows: “It could not have been the case that the person x murdered

²⁵⁴ See PhRMA quote above.

person y, because person x was not in the same country at the time of the murder”: thus the hoop test is failed and the explanation, “person x murdered person y,” is falsified (see Bennett and Checkel 2015, 17). Similarly, and using the same argument structure, it could not have been the case that the US made concessions in the form of intentional weakness in the definition of utility if evidence suggests that Canada did not at the time know it was receiving a concession. In other words, if we can show conclusively that Canada was not extracting a concession on this point then we know that the neoliberal hypothesis is false. It cannot pass this essential hoop test: “did Canada think it was receiving a concession on IP rather than making a concession?” In actuality, there is no evidence to suggest that either party could have foreseen this course of events with respect to patent invalidations.

If we look at one of the more comprehensive accounts of the NAFTA negotiation on record it seems that Canada’s experience with the earlier Canada US Free Trade Agreement informed its positions on intellectual property (Cameron and Tomlin 2000). Canada had resisted many intellectual property reforms as part of the FTA and was clearly the party making the concessions on IP in NAFTA, including but not limited to the effective prohibition on compulsory licenses (Ibid, 47). Canada did secure concessions from the US in the form of IP exemptions for its cultural industries, but the IP concessions ended there.

Negotiator accounts are also instructive. Upon examination of a pre-TRIPS/NAFTA 1989 “wish list” of benefits which US intellectual property owners sought, Canada’s lead negotiator on intellectual property, John Gero, noted the extent of the US win on IP: “A quick glance at the minimum substantive requirements of the

TRIPS Agreement and NAFTA indicates that virtually all of these goals have been accomplished and surpassed” (Gero and Lannen 1995, 93-4). This alone is sufficient basis to reject the neoliberal hypothesis of cooperation accommodation: Canada thought it was making a concession on IP not getting one in the form of lax definitions on IP. Gero has no incentive or reason to exaggerate the extent of the US win on IP. And if Canada did not know it was receiving a concession how could there be one? Clearly the hoop tests on neorealism and neoliberalism fail. The US was not bearing the costs of, or facilitating, cooperation. There was no robustly efficient or functional harmonization of standards, but only imprecise language on utility that seemed sufficiently broad from the US perspective to protect all patents capable of industrial application. Nevertheless, this allowed considerable room for domestic judicial interpretation and thus we see cross-national divergence of patentability outcomes.

There are probably several constructivist hypotheses that could be argued for the limiting of patent scope discussed above. The most central to the discussion in Chapter Two is that Canadian norms and identities were powerful enough to trump the material concerns (potential trade retaliation) related to TRIPS/NAFTA non-compliance. A relevant hoop test for a constructivist hypothesis is thus: for norms and identities to be determinative of a narrowing of patent scope then they should at least be cited or apparent in the key rulings.²⁵⁵ Looking first to the judgment and formative legal test set out in *Wellcome (2002)* we see that the Supreme Court was actually finding in favor of the patent owning *brand* pharmaceutical manufacturer. In setting out the test for sound

²⁵⁵ This is modeled after a normative hoop test outlined by Bennett (2015) where he argues “it would be hard to sustain the [normative] interpretation if there was no evidence that normative concerns were even raised” (Bennett 2015, 279).

prediction, the ruling takes pains to outline its balanced nature and that it is designed to uphold the “public interest”:

The doctrine of “sound prediction” balances the public interest in early disclosure of new and useful inventions, even before their utility has been fully verified by tests, and the public interest in avoiding cluttering the public domain with useless patents and granting monopoly rights in exchange for speculation or misinformation...The disclosure made in the patent was and is of real use and benefit and Glaxo/Wellcome, by making the disclosure, fulfilled its side of the bargain with the public. It was therefore entitled to legal protection for what it disclosed...²⁵⁶

Irrespective of what *Wellcome (2002)* has been used to justify and its many normative elements, this ruling was not an ideological or normative assertion against a predatory patent owner. The prohibition on post-patent evidence does not appear to be an intentional reaction to an obvious or flagrant legal transgression, but rather a guideline to discourage speculative patenting in the future. Importantly, the ruling aimed to uphold the institution of intellectual property rights as a *social bargain* with the public. But at the same time, it does meaningfully impact TRIPS/NAFTA in so far as it limits what evidence can be used to establish utility. Sound prediction of utility is explicitly framed as a provision in the public interest. It also asserts the power of the judicial branch to determine and reconstruct the promise of the patent retrospectively.

This assertion of authority by the court speaks to its self-identity as the preservers of that “public interest.” It establishes a legal test that considerably narrows the very broad definition of utility under TRIPS/NAFTA and is not reflected anywhere in any iteration of Canada’s *Patent Act*. It reframes the rules to reflect the court’s interpretation of how patentable value ought to be defined and the evidence that should be available at the time of patent filing. The patent owner’s IP is valid in the court’s view precisely

²⁵⁶ *Apotex Inc. v. Wellcome Foundation Ltd.* [2002], SCC docket 28287, accessed February 20, 2014 <https://scc-csc.lexum.com/scc-csc/scc-csc/en/2020/1/document.do>

because disclosures in the patent fulfilled its public bargain, not because it was capable of industrial application.

The normative language in the decision regarding “public interest,” preventing “useless” or “speculative” patents, and striking a public “bargain,” clearly cannot be used to dismiss the constructivist hypothesis. There is enough evidence in this key passage to satisfy the constructivist hoop test. The judicial positioning would seem to suggest that these social norms informed the decision and outcome at the critical juncture of *Wellcome*. However, unlike a failed hoop test, passing one cannot form the basis of a positive inference (Van Evera 1997, 32). Reference to norms and exhibition of identities is a necessary but not a sufficient condition to affirm the constructivist hypothesis.

In summary, it is highly probable that normative principles and identities impacted the original ruling that set the marker for subsequent promise utility doctrine patent invalidations. However, this ruling did not actually have a limiting effect on market exclusivity because it was positive for the patent owner. It did provide the historical basis for future material outcomes as subsequent rulings cited and were linked to *Wellcome* (2002). Neorealist and neoliberal alternative hypotheses are not instructive but constructivist norms and identities cannot be dismissed.

Policy Feedbacks Shaping the Evolution of IP Standards

This section explores the issue of how the local policy evolution identified in previous sections feeds back onto the international stage. One substantive impact of the Eli Lilly NAFTA challenge was a feedback effect on Canada’s trade diplomacy. Principally, this feedback was embodied in Canada’s trade and investment agreement with the European Union. The *Lilly* investor-state dispute settlement (ISDS) case impacted the explicit text

of the agreement’s investment chapter in a late addition following an eleventh hour round of highly political negotiations. The text of the final negotiated outcome—pre-legal scrubbing—included the following “declaration” regarding an apparent exemption from investor state dispute settlement for intellectual property matters:

Declaration to Investment Chapter Article X.11 Paragraph 6

Mindful that investor state dispute settlement tribunals are meant to enforce the obligations referred to in Article X.17(1): Scope of a Claim to Arbitration of Chapter x (yyy), and are not an appeal mechanism for the decisions of domestic courts, the Parties recall that the domestic courts of each Party are responsible for the determination of the existence and validity of intellectual property rights. The Parties further recognize that each Party shall be free to determine the appropriate method of implementing the provisions of this Agreement regarding intellectual property within their own legal system and practice. The Parties agree to review the relation between intellectual property rights and investment disciplines within 3 years after entry into force of the agreement or at the request of a Party. Further to this review and to the extent required, the Parties may issue binding interpretations to ensure the proper interpretation of the scope of investment protection under this Agreement in accordance with the provisions of Article X.27: Applicable Law and Rules of Interpretation of Chapter x (Investment).²⁵⁷

This is in direct response to Eli Lilly’s challenge to Canada. It specifically refers to the primacy of the court in the determination of patent validity. It also attempts to preserve room for parties to implement IP provisions according to domestic legal system and practice. The exclusion of this declaration from the body of the text calls its future impact into some question. It would seem to provide a quotable argument for respondent states to argue IP’s exclusion before ISDS tribunals; however, the full practical implications of this language will only be apparent with time.

This statement did not appear in earlier leaked iterations of the CETA text. It contains consistent language with Canada’s *Statement of Defense* in the *Lilly* case

²⁵⁷ *Consolidated CETA Text*, Published by the European Commission, September 26, 2014, at page 185, accessed February 20, 2015, http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf

regarding the existence and validity of IP. ISDS is not an “appeal mechanism” for IP decisions of domestic courts. The notion of a national review mechanism and binding interpretations of the scope of investment protections is also an interesting mitigation of unbridled investor protection. However, it is not entirely clear how this additional mechanism will work in practice. It is also unclear why this is included as a declarative appendix to Expropriation (Article X.11) and its paragraph dealing with IP (paragraph 6). This was a point of political discussion and would seem to represent a win for the EU and US IP-producing sectors. Paragraph 6 under Expropriation X.11 reads:

For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation.²⁵⁸

Paragraph 6 in the final CETA expropriation text was originally proposed by the EU to mirror the NAFTA text. This was added to the investment chapter somewhere between a November 21, 2013 leak²⁵⁹ and an April 7, 2014 leak.²⁶⁰ The explicit connection to TRIPS standards here is important because it does not rule out ISDS arbitration for national action on IP that might be inconsistent with TRIPS. Exactly who decides this is presumably an arbitration panel, which entails an ISDS hearing, and ultimately, that IP will indeed be an issue to be mediated in that venue. Including the declaration directly in the section on Expropriation X.11 would have enhanced clarity here. Alternatively, it could have been included in a similar manner as *Annex X.43.1 - Exclusions from Dispute*

²⁵⁸ Ibid at 159.

²⁵⁹ Leaked CETA Investment Chapter with party mark-ups as of November 21, 2013 http://eu-secretdeals.info/upload/COM-doc-CETA_investment-protection-newText-Nov-21-2013_clean.pdf

²⁶⁰ Leaked CETA Investment Chapter with party mark-ups as of April 7, 2014 http://eu-secretdeals.info/upload/COM-doc-CETA_investment-protection-newText-Nov-21-2013_clean.pdf

Settlement, which protects decisions under the *Investment Canada Act* from ISDS. However, this lack of clarity is also a result of CETA's direct adoption of NAFTA language structure.

CETA Chapter X, paragraph 6 is an artefact and legacy of similar provisions in NAFTA that exempted compulsory licenses and the revocation of IP from the definition of expropriation (NAFTA Chapter Eleven: Investment; Article 1110 (7)), provided it was compliant with NAFTA's intellectual property Chapter 17: "This Article does not apply ...to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property)."²⁶¹ In other words, CETA adopted NAFTA with respect to the definition of expropriation and the link to TRIPS compliance. This demonstrates why, from an historical perspective, these agreements and language need to be considered together. NAFTA Chapter 17, which was based on a late draft of TRIPS, also performs the same function as the "consistency with" qualifier to the statement that would otherwise limit IP's consideration under ISDS. This is why one of Canada's arguments in the Lilly case—that the arbitration panel has no jurisdiction—is up for debate. The open question is whether a NAFTA Chapter 11 dispute settlement tribunal has jurisdiction to hear an IP-related expropriation case on its own assessment of whether an IP revocation is inconsistent with NAFTA Chapter 17; or, must it first defer to the mechanism for dispute settlement in Chapter 17 (intellectual property) which is outlined in NAFTA *Chapter 20, Institutional Arrangements and Dispute Settlement Procedures*. Canada's lawyers advance a compelling argument for the latter. But similarly to CETA, there

²⁶¹ See also CETA X.11 paragraph 5, which contains the same language and exemption as NAFTA. *Consolidated CETA Text*, Published by the European Commission, September 26, 2014, at page 159, Accessed February 20, 2015, http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf

seems to be no specific guidance under NAFTA for “who decides” exceptions to the stated IP limits on expropriation. A Chapter 11 tribunal could very well interpret this to be within its purview.

In CETA’s case, the same question of jurisdiction regarding the determination of consistency with the IP chapter could arise. This is not spelled out in the agreement text. It is interesting that Canada *was not* the party proposing that CETA mirror NAFTA on this issue. As illuminated in leaked trade documents, it was actually the Europeans who wanted this language to mirror NAFTA. Canada proposed the language of the exemption to expropriation read “except where the decision amounts to a denial of justice or an abuse of right.”²⁶² The EU alternative that was ultimately adopted mirrors NAFTA²⁶³ in tying expropriation exemptions for IP to CETA’s own IP chapter. In other words, under both NAFTA and CETA, IP-related policies are normally exempt from the definition of expropriation but may not be if a government action is inconsistent with the IP chapter. CETA adds TRIPS as another essential point of national conformity. Figure 5.1 illustrates the various versions of the CETA agreement and where each of the relevant paragraphs was added in the negotiation process.

The final *Declaration to Investment Chapter Article X.11 Paragraph 6* cited above was not included until the final leaked version dated August 1, 2014. The EU in a

²⁶² “[CAN: For greater certainty, this Article does not apply to a decision by a court, administrative tribunal, or other governmental intellectual property authority, limiting or creating an intellectual property right, except where the decision amounts to a denial of justice or an abuse of right.]” http://eu-secretdeals.info/upload/2014/02/EU-Canada-FTA-Negotiations-Investment-chapter-4-April-2014_clean.pdf

²⁶³ Article X.11 Expropriation, Article 6 in the Final CETA text reads: “For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation.”

version dated September 26, 2014 subsequently released this.²⁶⁴ Prior to that release, negotiation over expropriation was discussed in offensive and defensive positioning in text at paragraphs 5 and 6. Canada did propose tying the definition of expropriation to TRIPS in an investment Chapter leak with national mark-ups dated November 21, 2013 in relation to compulsory licenses and the *revocation, limitation or creation of intellectual property rights*. But by April 4, 2014, that TRIPS reference was limited to compulsory licenses. Canada’s position on the *revocation, limitation or creation of intellectual property rights* was now tied to the nebulous “denial of justice” language cited above. The EU, however, appears to have insisted that both paragraph 5 (compulsory licenses) and paragraph 6 (*revocation, limitation or creation of intellectual property*) refer to TRIPS. Furthermore, the EU insisted that paragraph 6 also refer to the CETA IP chapter, per the model laid out in NAFTA. Canada would have been hard pressed to argue against its own model as laid out in NAFTA. Path dependence would seem to have *considerable* salience here.

Figure 5.1: Evolution of Key Passages in CETA Versions, Releases and Leaks²⁶⁵

CETA Version/Release	Declaration on IP re: expropriation	Expropriation para 5 (compulsory licenses)	Expropriation para 6 (revocation, limitation or creation of IP rights)
Leaked Memo – from European Commission (EC) to Trade Policy Committee November 6, 2012	Not yet an issue – negotiators still focused on <i>Canada Investment Act</i> , financial services exemptions, and scope of ISDS	Not discussed, only main positions on IP	Not discussed
Leaked Investment	Not yet included	CA proposes ²⁶⁶ language linked to NAFTA/TRIPS	Not yet included

²⁶⁴ *Consolidated CETA Text*, Published by the European Commission, September 26, 2014, at page 185, Accessed February 20, 2015, http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf

²⁶⁵ In addition to the leaks and releases in this table there were other important leaks of the CETA IP Chapter, as well as the consolidated section on investor state dispute settlement February 4, 2014 and April 3, 2014.

CETA Version/Release	Declaration on IP re: expropriation	Expropriation para 5 (compulsory licenses)	Expropriation para 6 (revocation, limitation or creation of IP rights)
Chapter with national mark-ups November 21, 2013		EU proposes similar with addition of WTO ²⁶⁷	
Leaked Investment Chapter with national mark-ups April 4, 2014	Not yet included as a separate declaration: Proposed by EU as “separate annex or joint understanding;” Similar text to declaration proposed by Canada to be in text ²⁶⁸	Yes – confirmed per the EU proposed text	Canada proposes vague language re: “denial of justice or an abuse of right.” EU proposes as “separate annex or joint understanding;” per the NAFTA model: “to the extent that these measures are consistent with TRIPS and the IPR Chapter of CETA”
Leaked CETA Text (EU Member) marked “Final” August 1, 2014	Yes – Detailed declaration to Expropriate para 6 as quoted above	Yes	Yes- Per EU language, but in main treaty text as section 6 rather than separate annex; ²⁶⁹ Tied to CETA IP chapter.
Published CETA Text by European Commission September 26, 2014	Yes	Yes	Yes
Final CETA text following legal scrub 2016	Yes	Yes	Yes

²⁶⁶ “[CAN: 5. This article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights or to the revocation, limitation or creation of intellectual property rights, to the extent that these actions are consistent with the TRIPS Agreement. For greater certainty, a determination that these actions are inconsistent with the TRIPS Agreement does not establish that there has been an expropriation.]” http://eu-secretdeals.info/upload/COM-doc-CETA_-investment-protection-newText-Nov-21-2013_clean.pdf

²⁶⁷ “[EU: 5. This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, to the extent that such issuance is consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights in Annex 1C to the WTO Agreements (‘TRIPS Agreement’).]” http://eu-secretdeals.info/upload/COM-doc-CETA_-investment-protection-newText-Nov-21-2013_clean.pdf

²⁶⁸ “[CAN: For greater certainty, this Article does not apply to a decision by a court, administrative tribunal, or other governmental intellectual property authority, limiting or creating an intellectual property right, except where the decision amounts to a denial of justice or an abuse of right.]” http://eu-secretdeals.info/upload/2014/02/EU-Canada-FTA-Negotiations-Investment-chapter-4-April-2014_clean.pdf

²⁶⁹ Text per CETA Leak August 1, 2014: “For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation.”

One of the most interesting leaks on the CETA IP and investment negotiation was an earlier memo from the European Commission to the EU Trade Committee. The memo clearly outlines that the scope of investor-state dispute settlement was a key controversy as early as November 2012. Regarding pharmaceutical patents, the memo suggests the highly politicized nature of the discussion. There was a clear issue linkage or tradeoff between Canada's offensive agricultural-related positions:

These [European intellectual property rights] requests are strongly supported by Canada's own research-based pharmaceutical industry, but strenuously opposed by generic drugs producers, who are attempting to frame the debate in Canada in terms of higher costs for the public health services. Given the high degree of political sensitivity, both at the Federal and Provincial level, Canada has not made any move on this issue in the negotiations and clearly any decision on the EU [intellectual property rights] requests will be taken at the highest political level at the end of the negotiations. ... Any Canadian move will be linked to the negotiation result on the offensive agricultural market access issues of Canada, and will condition our ability to deliver on all three [intellectual property rights] issues.²⁷⁰

The linking of the IP and agricultural items under the CETA negotiation is indicative of the high-politics associated with these knowledge-economy discussions. IP is controversial in many sectors, however, it is particularly so for pharmaceuticals. This is due to the fiscal exposure that provincial governments have to IP regarding drug costs and Canada's large and influential generic pharmaceutical industry.

As identified in earlier chapters, the generic sector has a long political history in Canada and has benefitted greatly from previous policy decisions regarding compulsory licenses. It has also benefitted from Canada's comparatively less protective IP regime

²⁷⁰ The three EU asks include: 1) patent term restoration, 2) extended period of data exclusivity, and 3) introduction of a right of appeal under Canada's marketing authorization regime. Note the latter is also reflected in the USTR 301 reports. Memo – from EC to Trade Policy Committee. Nov 6, 2012 Leak available at *LaPresse.ca*, accessed April 2, 2015, http://www.lapresse.ca/html/1633/Document_UE_2.pdf.

(compared to those found in the US and EU). The fact that the CETA IP decision went to “the highest levels” politically is no coincidence. It is reflective of the power of an institutionalized interest coalition and strong generic drug sector that has resulted from many previous industrial policy decisions. The fact that Canada has historically paid some of the highest prices internationally for generic medicines is also interesting (Law 2013; Law and Kratzer 2012). This provides the generic sector with a substantial base of power both to challenge essentially every valuable patent as well as to lobby the government for favorable treatment. The lobbying effort made on CETA and key concessions to the generic industry reflect the historical power and institutionalization of that sector in Canada. Canada resisted EU proposals for up to five years of patent term restoration²⁷¹ and this was ultimately limited at (up to) two years. It also rejected the proposal of extending data protection to new uses for already approved drugs. Concessions notably included exceptions to IP violations for generic exports and ending so-called “dual-litigation.”²⁷² This will involve substantial reform and potential abolishment of the patent linkage regulation. As in the past, the government walks a fine line to balance interests on these reforms. Many of the most important details will be worked out in regulations following the agreement.

Canada clearly wants ongoing ISDS protection for Canadian investments but the experience with NAFTA ISDS has complicated its pursuit of that objective. In 2014 Canada’s International Trade Committee undertook a study and published the following

²⁷¹ Richard Dicerni, Deputy Minister, Industry Canada, Advice to the Minister – Secret - CCM 230912 “Meeting with the Canadian Generic Pharmaceutical Industry Association (CGPA).”

²⁷² Government of Canada, *Technical Summary of Final Negotiated Outcomes: Canada-European Union Comprehensive Economic and Trade Agreement, Agreement-in-Principle* October 18, 2013, , accessed April 2, 2015, <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/ceta-aecg/ceta-technicalsummary.pdf>

recommendation on ISDS: “That the Government of Canada continue to negotiate strong investor-state dispute settlement and investment protection measures into trade agreements to provide predictability and stability for Canadian investors.” In practice under a majority government such committee reports have little policy influence and often simply *reflect* the government’s positions and intent. On October 15, 2014 the government published a response to the committee’s CETA report. This included explicit support for the committee’s recommendation and some positioning regarding the attempt to “balance” interests:

The Government of Canada supports this recommendation....In all of its investment-related negotiations, the Government of Canada pursues a high standard of protection for its investors and seeks to include a robust investor-state dispute settlement (ISDS) mechanism. Doing so establishes a stable and predictable rules-based investment climate and provides access to an independent, impartial and timely process for the resolution of disputes... The Government also negotiates exceptions and reservations to its investment agreements and free trade agreement investment chapters that preserve existing and future policy flexibility in sensitive areas, particularly in the areas of health, the environment, culture and social services.²⁷³

Even if not a meaningful exercise from a substantive policy perspective, this back and forth pageantry between government and parliamentary committees is useful as a venue to articulate and legitimize government positions on highly political issues. The lack of clarity on the practical impacts of the negotiated “exceptions and reservation” to ISDS and intellectual property protection reflect the challenges and politics of providing balance in the knowledge economy.

²⁷³ Government of Canada, *Government Response to the Second Report of the Standing Committee on International Trade: Canada-European Union Comprehensive Economic and Trade Agreement*, accessed May 20, 2015, <http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6726255&Language=E&Mode=1&Parl=41&Ses=2>

Conclusion

In summary, it is productive to think of the ratification of NAFTA and TRIPS not as a discrete outcome, but rather as the first step in a long process of implementation. International standards interact and sometimes clash with domestic institutions on an ongoing basis. Canadian legal institutions are resilient in the face of international regulatory standards and bilateral pressure. The evolution of IP case law and the political fallout show how standards evolve to reflect local institutions as much or even more than the international standard. TRIPS implementation required many modifications to Canada's *Patent Act* but did not alter the definition of utility nor diminish the power of judicial institutions to further constrain the breadth of patentable utility. Long-standing practices were subsequently institutionalized in the form of a specific legal doctrine. This implied rules for case-by-case interpretation that contrasted with the broader TRIPS standard regarding 'industrial application.' Rules of evidence excluding post-patent proof in 'sound prediction' cases made evidence of commercial success moot.

Process tracing various logical tests shows the utility of historical institutionalism (HI). Canada's response to US and EU pressure demonstrates how local power can manifest despite considerable pressure from powerful international actors. These issues were pursued in an international investment dispute forum with implications for trade diplomacy and CETA. CETA is widely regarded as the model for next-generation trade deals. The fallout from NAFTA litigation has impacted the very future and legitimacy of ISDS going forward.

Regulatory standards build on past regulations and trade agreements build on past trade agreements. Trade treaties are an important political outcome but their

implementation is equally important as this process sets the parameters for the intersection of global and domestic standards. As one standard morphs into another, we see clear policy feedback and path dependence as would be expected under an HI hypothesis. Domestic institutions can retain considerable influence as part of this process.

Chapter 6 Institutional Feedback: The Procurement Dimension

This chapter examines procurement policy feedbacks related to the expansion of trade-related intellectual property (IP) rights in Canada. The new international IP regime and a proliferation of new, patented technologies would have clear financial impacts for Canadian health insurers. The chapter makes three arguments. First, in response to budgetary challenges, Canadian decision-makers converted nascent civil society and academic institutions and elevated them to become important institutions of the state. Second, this layering of institutions had a significant constraining impact on the public market for pharmaceuticals. The success of these public institutions has attracted the attention of Canada's private drug insurers who do not yet have similar capacity and have increasingly tried to leverage the power of public institutions.²⁷⁴ Third, Canada has played a leadership role in an international diffusion of similar ideas and institutions that were adopted in different ways in accordance with existing national circumstances. This diffusion can be attributed to epistemic cooperation and the functionality of the ideas themselves, not due to market power.

Market power theory would predict that small market powers are not likely to significantly mitigate trade commitments that are contrary to the interests of larger

²⁷⁴ Public spending on prescription drugs constituted approximately 48% of the prescribed drug market in 1992 around the time of TRIPS negotiation. This had fallen to approximately 43% in 2015, a shift that reflects various factors including government cost-containment. Due to the success of public institutions, private insurers have actively tried to adopt and leverage public institutional power of both this procurement assistance regime and the price regulation institutions discussed in earlier chapters. Canadian Institute for Health Information (CIHI), "Drug Expenditure in Canada, 1985 to 2010," 11, accessed August 16, 2016, http://publications.gc.ca/collections/collection_2011/icis-cihi/H115-27-2010-eng.pdf; Canadian Institute for Health Information (CIHI), "Prescribed Drug Spending in Canada, 2013" 11, accessed August 16, 2016 https://www.cihi.ca/en/pds2015_pubsumm_en.pdf

market powers. For market power to hold, we would expect global standards advanced by the hegemon to essentially alter or replace domestic rules without strong compensatory domestic institutional layering or conversion. Institutional repulsion and resistance through these feedbacks should not be powerful. Furthermore, regulatory initiatives should not generally be successful internationally unless they are advanced by a major market power. Policy diffusion should be a function of power. We would certainly not expect to see domestic mitigating institutions of smaller powers diffuse internationally. Evidence of either would be a smoking gun that other important factors beyond market power are needed to explain international regulatory diffusion.

Conversely, historical institutionalism suggests that past policy decisions create policy feedbacks that impact politics: actors adopt strategies that reinforce the logic of the system (Thelen 1999, 2003; Pierson 1993). For historical institutionalism to have validity as an alternative to market power or as part of a pluralist framework, we would expect to see strong domestic institutional feedbacks (domestic reinforcement) that are successful in resisting or repelling the impact of international standards. Evidence of this would strongly suggest that historical institutionalism is not “bunk.”²⁷⁵

For this to be most convincing from a research design perspective, domestic actors should have capacity to respond to powerful exogenous pressures. HI would suggest that actors adapt to new challenges by converting nascent institutions or layering new institutions on top of existing ones. Indeed, the emergence and evolution of Canadian procurement assistance institutions is a useful empirical case to evaluate

²⁷⁵ As identified in Chapter 1, the question “Is Historical Institutionalism Bunk?” was raised by Drezner (2010). Furthermore, evidence that local policy feedbacks within a smaller power actually help to *create* global political outcomes in an international diffusion process where standards are adopted in path-dependent ways would tend to support an historical institutionalism hypothesis.

whether institutional layering and conversion have significant domestic and international impacts. This is because these institutions had very modest beginnings, low financial resources, and initially lacked a direct connection to core state decision-making processes. They were not developed by great powers who control major markets as would be required under a market power theory (Drezner 2007, 5).²⁷⁶

The chapter starts process tracing in 1989 around the emergence of Canadian “health technology assessment” (HTA) institutions. HTA is defined as “systematic evaluation of a medical or health technology for evidence of its safety, efficacy, effectiveness, cost, cost-effectiveness, and ethical and legal implications, both in absolute terms and in comparison with other competing technologies” (Stephens et al. 2012, 29).²⁷⁷ HTA in Canada and in other countries was derived from the “evidence based medicine” (EBM) movement.²⁷⁸ EBM was a Canadian academic medical innovation and is defined as the “conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients... integrating individual clinical expertise with the best available external clinical evidence from systematic research” (Sackett 1997). The chapter then shows how EBM and pharmaceutical HTA institutions narrowed the number of available technologies and the conditions under which they would be available for a significant portion of the patented health products market.

²⁷⁶ See discussion below.

²⁷⁷ This definition is favorable to the World Health Organization (WHO) definition: “the systematic evaluation of properties, effects, and/or impacts of health technology [and] is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology in a systematic, transparent, unbiased and robust manner” (World Health Organization 2015, 8). The WHO definition lacks sufficient specificity and omits that comparative cost-effectiveness analysis has become an essential component of HTA as practiced in Canada and Europe.

²⁷⁸ EBM and evidence-based policy making were the principles behind the rapid emergence and institutional adoption of “health technology assessment” (HTA) institutions.

The chapter then conducts a within-case comparison of these institutions vis-à-vis Canada's private drug insurance market, which has not been able to similarly mitigate its exposure to the IP regime. It argues the power and institutional capacity of public institutions by showing how private market actors have increasingly attempted to leverage them. Per an HI approach, public market sequencing of capacity development has had a significant impact on regime impacts within the same system. Finally, the chapter traces the international diffusion of Canadian ideas and cost-effectiveness methodologies. Canada's leadership helped many other countries adopt similar institutions to mitigate the full effect of international IP standards and the related costs of patented pharmaceuticals. Policy diffusion was not completed via a formal regime underwritten by market power, but through international epistemic cooperation.

In comparison to earlier chapters, the chapter traces policy processes more removed from actual trade deals regarding time and sphere-of-governance. However, process tracing methodology encourages a diversity of evidence gathering to help uncover causal mechanisms that may be somewhat hidden or non-obvious (Bennett and Checkel 2015). Also, process tracing must not be limited to "micromechanisms within processes" and should thus avoid "temporally restricted accounts" (Pierson 2004, 101). While removed from trade negotiations, the chapter argues that the state's adoption of HTA is a critical policy feedback to trade-related IP protections.

How HTA Institutions Narrow the Effect of Patent Protection

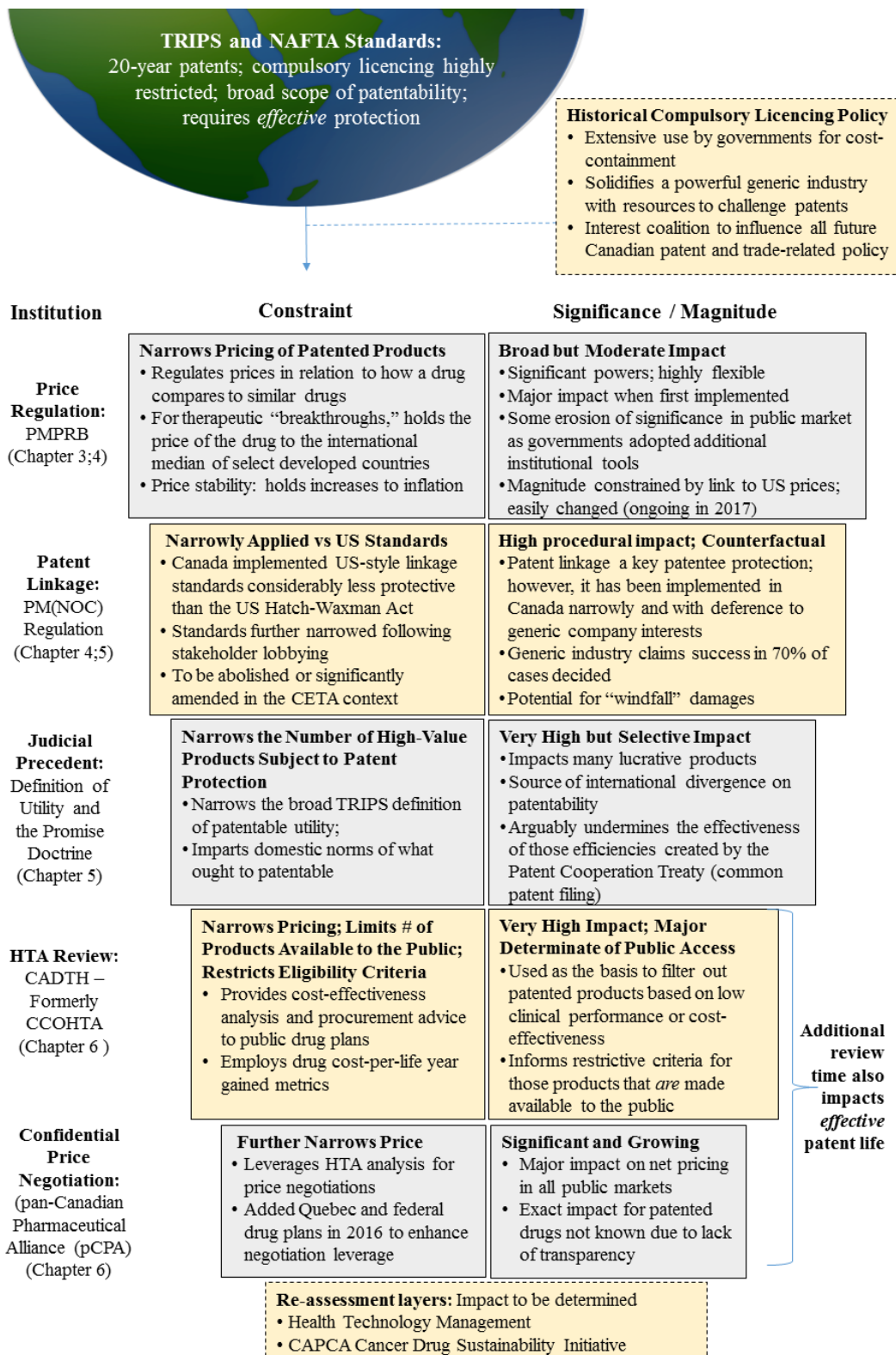
This section argues a point that is highly logical but is not made explicit by the health technology assessment (HTA) community and its literature. HTA institutions, particularly those that assess pharmaceuticals, have been adopted as an inherent state

response to the proliferation of patented products under increasing IP protections.²⁷⁹ It is useful to illustrate how HTA fits into the broader system and other institutions cited in earlier chapters. Figure 6.1 depicts core pharmaceutical system institutions in Canada at a high level and details how each contributes to narrowing the IP regime.²⁸⁰ The section traces the origins and practical impact of these institutions. They increasingly provided valuable procurement assistance to public health insurers to determine what patented technologies would be purchased or reimbursed by publicly funded government health plans. The institutions had considerable success in narrowing the scope of public insurance plan exposure to expanded IP protections. It then argues that this policy evolution exemplifies layering and conversion, which are the key dynamics of change under historical institutionalism (Thelen 2003).

²⁷⁹ This does not mean that HTA does not also accomplish its more explicit aims related to evidence-based medicine, enhancing the quality of patient care, or supporting rational pharmaceutical decision-making. It should be noted that pharmaceutical costs are closely related to intellectual property rights and the costs associated with research and regulatory approval. The cost of raw chemical materials is most often negligible. In absence of IP rights, cost-based HTA would have little if any role in policy decision-making. Evidence might still be used to inform clinical decisions, but HTA as it is known in Canada and Europe would not likely exist.

²⁸⁰ Where price regulation and other institutions examined in earlier chapters impact both the public and private market, additional institutional layers have been subsequently added in the public market to further address the assessment and procurement of patented medicines (see Figure 6.7).

Figure 6.1: How Canadian Institutions Constrain International Regime Standards



Origins of Health Technology Assessment Institutions in Canada

This section explores the emergence and sources of HTA in Canada. It shows that HTA's early proponents were careful to grow the institution incrementally and allow it to demonstrate its utility and reach a critical mass. EBM and HTA were then repurposed to take on the more complex and political task of evaluating pharmaceuticals. While HTA in Canada was originally envisioned for medical devices and procedures, its adoption and role in Canada has been *most* apparent for patented pharmaceuticals.

In December 1989, Canadian federal, provincial and territorial (F/P/T) Ministers of Health agreed to establish and jointly fund the Canadian Coordinating Office for Health Technology Assessment (CCOHTA). The new institution would be led by a leading proponent of HTA in Canada Dr. Devidas Menon with a mandate to “provide Canadian health care policy decision makers with evidence-based information on emerging and existing medical devices” (CADTH 2009). CCOHTA was originally set up as a three-year pilot with a modest budget of \$500,000 shared between federal and provincial governments with contributions determined on a population basis (Battista et al. 1995a, 77; Battista et al. 1995, 102).²⁸¹ Under Canadian federalism, authority for health is fragmented among provinces. As such, CCOHTA was to play a coordination role between parallel provincial bodies that had emerged in Québec in 1988 (Québec Conseil d’Evaluation des Technologies de la Sante (CETS)) and were emerging in British Columbia, Alberta, and Saskatchewan (Battista and Hodge 1995, 289). The “preferred target audience” for this work was “clearly... policy makers” who had system-

²⁸¹ CCOHTA's mandate was to “provide Canadian health care policy decision-makers with evidence-based information on emerging and existing medical devices.” CADTH website, accessed September 5, 2016, <http://scientificadvice.cadth.ca/en/cadth/history>.

level authority (Battista, public remarks, 2015). Governments and HTA agencies jointly prioritized topics for review (Ibid).

CCOHTA's early focus on devices, as opposed to pharmaceuticals, appears to have been a matter of both strategy and practicality given the modest allocations from government:

Generally at the beginning... I remember the conversations that we were having here when CCOHTA was created and as well when the Québec Council²⁸² was created, there was some fear that the domain of pharmaceuticals, being so vast, would very quickly overwhelm, the capacity to evaluate, from these nascent organizations...At the beginning of these organizations the scientific capacity is minimal, the resources are modest...looking at what CADTH has become today, you realize that this was certainly the right thing to do, this was the wise thing to do, because it has grown so much in this country, and around the world, in fact (Battista, public remarks, 2015).

In other words, there was a conscious effort among early proponents to keep the scope of Canadian HTA manageable without taking on the more onerous and complex task of evaluating pharmaceuticals. This allowed CCOHTA to develop its institutional capacity, reputation, and utility to policy makers (Battista et al. 1995; Battista, public remarks, 2015). Battista seems to attribute CCOHTA's success to this sequencing of institutional development (Battista, public remarks, 2015).

HTA and evidence-based health policy making in general was derived from the EBM movement.²⁸³ The movement was principally aimed at strengthening “standards of

²⁸² Québec Conseil d'Évaluation des Technologies de la Santé (CETS).

²⁸³ This movement was pioneered by David Sackett, his student Gordon Guyatt who coined the term and many other collaborators including, but not limited to, Andrew Oxman, Brian Haynes, Deborah Cook, Mitchell Levine, Iain Chalmers, Anthony Culyer, and others within the “Evidence-Based Medicine Working Group” (for a full list of participants as of November 1993 see: Oxman, Sackett and Guyatt 1993). While EBM and HTA are closely linked, other important pioneers including Devidas Menon (Canada), Renaldo Battista (Canada-Quebec), David Banta (US), Egon Jonsson (Sweden, later Canada), are perhaps more associated with HTA institutions than strictly EBM. Other important thinkers such as Archie Cochrane (UK) also helped to inform the EBM movement.

clinical practice” and to “bring more certainty to clinical decision making” around the “best available evidence” (Sur and Dahm 2011). An epistemic community centered on the ‘Evidence-Based Medicine Working Group’ advanced much of the early work on EBM.²⁸⁴ This group was supported by grants to EBM pioneer Dr. David Sackett in the late 1980s and early 1990s (Oxman, Sackett, and Guyatt 1993).²⁸⁵ As is typical of government research grants to academics in Canada, the government did not actively direct, but rather encouraged this emergent area of practical scholarship to develop at arms-length. Under the leadership of Sackett, Guyatt, and others, the EBM community grew organically and developed tools and methodologies that would later be adopted directly by governments when purchasing patented technologies. Sackett also helped to diffuse EBM to Europe.²⁸⁶

It is important to note that the original purpose of EBM was not necessarily related to government cost-containment, but rather enhancing standards and quality of care. In fact, there was some concern within the EBM community that its principles and methods would be repurposed for such objectives:

²⁸⁴ This epistemic community of clinicians and academics (clinical epidemiologists) grew around McMaster University and published extensively in the 1980s and early 1990s (Ibid). Their publications notably included a series of ‘how to’ articles in the Journal of the American Medical Association (JAMA) stylized as “Users’ Guides to the Medical Literature.” These were aimed at busy clinicians who wanted to improve patient outcomes by incorporating evidence into their day-to-day medical practice (Evidence-Based Medicine Working Group 1992; Oxman, Sackett and Guyatt 1993). For a full bibliography of the JAMA ‘Users’ Guides to the Medical Literature’ see University of Toronto Evidence-Based Medicine research guide, “Evidence Based Medicine” accessed August 29, 2016, <http://guides.library.utoronto.ca/c.php?g=250646&p=1671396>.

²⁸⁵ Grants included the Ontario Government’s Trillium Clinical Scientist Award. Sackett founded Canada’s first department of clinical epidemiology at McMaster University in 1967. Canadian Medical Hall of Fame, accessed August 28, 2016, <http://cdnmedhall.org/inductees/dr-david-sackett>. Sackett had also received \$500,000 from Ontario to establish a General Internal Medicine (GIM) program for the McMaster Region that would be designed around EBM principles (Sackett 2015). Critical details on the history of the evidence-based medicine movement were articulated in a written self-interview by Sackett in the final months of his life (Sackett 2015).

²⁸⁶ In 1994, he left McMaster to take up a position at Oxford University and helped to entrench EBM approaches despite considerable resistance from parts of the British medical establishment (Sackett 2015, 44-54).

Some fear that evidence based medicine will be hijacked by purchasers and managers to cut the costs of health care. This would not only be a misuse of evidence based medicine but suggests a fundamental misunderstanding of its financial consequences. Doctors practicing evidence based medicine will identify and apply the most efficacious interventions to maximize the quality and quantity of life for individual patients; this may raise rather than lower the cost of their care (Sackett et al. 1996).

In other words, there are many instances where EBM, properly practiced, will actually increase costs within a health system. For example, this could be the case for the introduction of effective new health technologies or medical processes that require incremental health care practitioner hours and resources. However, there are also clear cases where EBM can be used to limit inappropriate or wasteful health care spending, or even be ‘hijacked’ to ration access to patented technologies. This requires the adoption of a *policy* at some level of governance regarding appropriate or inappropriate practice.

Evolution of HTA and its Incorporation Into Public Policy Processes

This section illustrates how Canada’s early HTA institutions gradually started to occupy space in high-level public policy planning processes. The timing of HTA’s expansion coincided with trade related intellectual property reforms under Bill C-91 (NAFTA-related amendments to the Patent Act) and pressing provincial concerns over future drug costs. The same committee of senior officials²⁸⁷ tasked with considering the provincial response to Bill C-91 also considered CCOHTA’s future role (O’Reilly 2001, 126). While not explicitly linked to trade and IP, Deputy Ministers of Health made CCOHTA a permanent institution and increased its budget. The institution also began to adopt a coordination role for pharmaceutical reviews. These reviews were part of provincial

²⁸⁷ This group included Provincial and Territorial Deputy Ministers of Health and reported directly to the F/P/T Conference of Deputy Ministers of Health.

pharmaceutical economic evaluation mechanisms that at the time were unique to Canada and Australia (Drummond, Jönsson, and Rutten 1997). The economic evaluation approach was noted in 1997 as a model for development in “free pricing” systems (UK, US), administered systems (France), and reference pricing systems (Germany, Netherlands, Sweden) (Ibid).

As described by Dr. Menon, HTA was explicitly “a field developed to support purchasing or coverage decisions” (Menon and Stafinski 2009). HTA was in some ways the systematization of EBM: “McMaster University in Hamilton, Ont., led the earliest developments in evidence-based medicine. Health technology assessment was...a natural extension of the production and use of evidence in system-level decision-making” (Menon 2015). Evidence-based policy is now almost taken for granted as obvious and desirable, but this was not always the case. For example, *policy* instituted by a government or health authority may be viewed as limiting the possibility for practitioners to exercise clinical judgment.²⁸⁸ However, new more expensive pharmaceutical products continued to enter the market following trade-related intellectual property reform. Concerns about demographic challenges posed by Canada’s aging population were also growing. In fairly short order, the utility of EBM and specifically HTA for patented pharmaceuticals became clear to government and most of the medical community. Clinical considerations regarding practitioner choice are still a concern, but seem to have lost priority to the concerns of curbing patented drug costs, countering aggressive pharmaceutical marketing practices, and managing the proliferation of new patented treatments.

²⁸⁸ This is the source of the concern over administrative ‘hijacking’ identified by Sackett above.

In parallel with the expansion of intellectual property protection under NAFTA and the draft TRIPS, Canadian policy makers in 1993 expanded CCOHTA's coordination mandate to pharmaceutical reviews. F/P/T Deputy Ministers of Health agreed to triple the institution's budget (CADTH 2009). CCOHTA was also entrenched as a "permanent" institution in 1993 (Sanders 2002). At that time, Canada's existing intergovernmental system of F/P/T cooperation was in the midst of considerable organizational shift to manage what were seen as the pressing health challenges of the day. Following the publication of the somewhat ominously titled "Blueprint to Ensure the Future of Health in Canada" in June 1992, F/P/T Deputy Ministers of Health established several different interprovincial advisory committees (O'Reilly 2001, 111). One of these focused on 'health service delivery' and explicitly aimed to link health care *costs* to health care *quality* (Ibid). This group of senior officials assessed the future and expanded mandate of the CCOHTA in light of what provinces were increasingly anxious over: "pharmaceutical utilization and cost" (Ibid, 123). In addition to considering CCOHTA's future role, this same Health Services committee of senior officials including Deputy Ministers of Health was also tasked with determining how provinces would manage expanded pharmaceutical patent protections under Bill C-91 (Ibid, 126). The abolition of compulsory licensing under a 20-year patent term was obviously a major concern²⁸⁹ for Deputy Ministers given the immense fiscal benefits Canadian provinces derived from them in the past (Eastman 1985; see discussion Chapter 2).

The expanded CCOHTA mandate into pharmaceuticals was not yet a formalized review process for all products entering the Canadian market. This would come later in

²⁸⁹ For example see House of Commons, Standing Committee on Industry, "Summary of Testimony," Fifth Report: Section 14 of the Patent Act Amendment 1992 (C-91) accessed January 3, 2016. http://www.parl.gc.ca/Content/HOC/Archives/Committee/352/indu/reports/05_1997-04/chap3-e.html

2002-2003 when CCOHTA was given the mandate to establish the “Common Drug Review” (CDR) and did so on a permanent basis in 2004.²⁹⁰ For the time being, CCOHTA continued to play more of a coordinating role to track and share the various studies being conducted locally by EBM academics, provincial cost-effectiveness review bodies, and similar international activities.

The early self-reflective literature of the HTA community identifies the following primary drivers of its adoption: health care costs, related information needs of policy makers, and a critical mass of epistemic expertise in the “evaluative sciences” including epidemiology and economics (Battista and Hodge 1995, 293-4). While these factors are not prioritized in the literature, it is interesting to note that HTA for pharmaceuticals has not developed to the same extent in the US where health care cost escalation was *most* acute in the early 1990s (Ibid). However, it did develop where an epistemic and institutional critical mass was also present, such as in Canada. Volunteerism, goodwill, and policy “champions” within that epistemic group were also critical to its development in Canada (Battista, public remarks, 2015).²⁹¹ Based on their early assessment of progress in HTA, Battista and Hodge (1995) note, “the science of technology assessment will benefit from institutions and mechanisms that foster interdisciplinary communications and collaboration” (294). Taken together, this suggests that structural cost factors are perhaps a necessary but not a sufficient condition for the emergence of

²⁹⁰ CDR would assess all new drugs and make recommendations to participating F/P/T governments regarding public coverage decisions (excluding the province of Québec which established its own parallel review mechanism). This decision-making process is commonly referred to as ‘formulary listing’ given that the process does not reflect direct ‘procurement’ *per se*, but rather a review for inclusion on a provincial formulary list of eligible drugs for reimbursement under public drug insurance plans.

²⁹¹ “With respect to emergence... with respect to the why?...clearly the notion of champions was absolutely key. You need people to really believe in the power of evidence in the decision making process... therefore a receptive policy environment and a maturation period where the champion will try to convince [was needed]” (Battista, public remarks, 2015).

HTA. However, as argued below, cost concerns were certainly behind the *repurposing* and *institutional adoption* of EBM principles and HTA to help manage patented pharmaceutical procurement.

How HTA Methodologies Constrain the Impact of Patented Pharmaceuticals

This section elaborates on the specific methodology of Health Technology Assessment (HTA) and how it is used to mediate demand for patented technologies. HTA bodies such as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) help guide government funding decisions and justify funding some technologies and not others. CCOHTA's role evolved within the Canadian health system to 1) increasingly consider pharmaceuticals, 2) increasingly play an evaluation and advisory role to government as opposed to a strict coordination role, and 3) become an important institution of the state to help manage costs. To reflect these new roles, CCOHTA was later renamed the Canadian Agency for Drugs and Technologies in Health (CADTH).²⁹²

A critical component of Canada's evaluation system was to link comparative clinical effectiveness research with cost metrics to produce comparative *cost-effectiveness* research. This contrasts with the US and Swedish systems that had earlier roots in general 'technology assessment.' However, cost-based clinical effectiveness research is expressly prohibited in US Medicare decision-making and Sweden explicitly did not aim to contain costs (Garber and Sox 2010; Jonsson and Banta 1995).

HTA is arguably an approach to ration access to publicly funded health technologies. However, the term "rationing" has political implications and therefore HTA

²⁹² This name change took effect in 2006 after the establishment of the Common Drug Review process. CADTH website, accessed September 5, 2016, <http://scientificadvice.cadth.ca/en/cadth/history>

is more frequently positioned as “evidence-based decision-making” or “evidence-based formulary review.” From a political perspective, it is much easier to grow or sustain spending than to push back against demand for health technologies or make painful expenditure reductions. Health spending cuts are particularly contentious due to the human element and the reality that the “baby-boom” demographic most associated with health care cost concerns is politically powerful and assertive within the electoral process. As a result, public health system managers in Canada have found it useful to have solid clinical and particularly *economic* evidence to justify specific health system decision-making and austerity measures. They appealed to expert processes to secure this.

In some ways, HTA reflects very sensible and prudent management, but it also reflects an attempt to de-politicize important spending decisions through expert analysis. Pharmaceutical HTA typically rewards those companies and patented technologies that produce technological and therapeutic advancements that can demonstrate they are cost-effective. The key metrics and methodologies used in HTA to establish cost-effectiveness are “quality-adjusted life years” (QALY) and comparative “incremental cost-effectiveness ratios” (ICERs). When considering the value of a treatment, QALY is a measurement that approximates the effectiveness of a therapy to extend life, adjusted for quality of life improvements. Where QALY is a unit of measurement, a *QALY threshold* is a policy statement about value and what should be regarded as cost-effective. As discussed by Menon and Stafinski, there are known general parameters or suggested

guidelines for QALY policy thresholds, but no hard data²⁹³ on their role in government decision-making processes:

A cost/QALY threshold was first suggested in 1992 in Canada. The proposed figure was \$20,000 per QALY (1992 dollars) for the threshold below which a new technology ought to be adopted, and \$100,000 per QALY for the threshold above which a new technology should not be adopted. A threshold figure that is cited now is US \$50,000 per QALY. However, there is no formal evidence that any of these boundaries has ever been accepted or implemented by any Canadian decision-making body. In fact, Laupacis has since stated that the traditional \$50K/QALY ‘would be considered relatively unattractive’ (Menon and Stafinski 2009, S14-19).

The key data that goes into calculating QALY is an expert clinical assessment of a drug or device’s therapeutic benefit. This assessment requires considerable medical and economic expertise.

HTA bodies are usually funded by governments but comprised of academics, health economists, and clinicians who make funding recommendations based on a product’s comparative therapeutic benefits and costs. An expert committee is responsible for this assessment.²⁹⁴ CCOHTA²⁹⁵ established an expert advisory body called the Canadian Drug Expert Committee (CDEC).²⁹⁶ CADTH also maintains a specific review process for oncology drugs called the pan-Canadian Oncology Drug Review (pCODR)

²⁹³ This contrasts with the system that has subsequently developed in the UK where ‘appropriate’ QALY thresholds are discussed much more openly. For example, the Drug “Appraisal Committee” of the UK National Institute for Health and Care Excellence (NICE) has discussed in public the relative appropriateness of cost per QALY between £20,000 and £30,000. Appraisal Committee Chairs have published on “special circumstances” that have warranted incremental cost-effectiveness above £30 000 per quality adjusted life year. The six factors include: condition severity; end-of-life considerations (since 2009); stakeholder persuasion; significant innovation; disadvantaged populations; and, clinical use for children (Rawlins, Barnett, and Stevens 2010).

²⁹⁴ This is similar to the Human Drug Advisory Panel (HDAP), the committee used by the Patented Medicines Prices Review Board referenced earlier (see Chapter 3).

²⁹⁵ Now called CADTH.

²⁹⁶ This body was originally called the Canadian Expert Drug Advisory Committee (CEDAC) but in 2011 was renamed the Canadian Drug Expert Committee (CDEC).

that has its own expert committee, the pCODR Expert Review Committee (pERC).²⁹⁷ CDEC and pERC expert committees review clinical and cost data submitted by manufacturers to assess a drug's therapeutic benefits and cost-effectiveness. These data are first compiled and analyzed by CADTH staff reviewers. The expert committees then make recommendations regarding coverage directly to government payers. A simple flow chart illustrating these institutions and expert committees is found in Annex D.

Cost is determined by the price of a therapy and the duration or course of treatment required. Pharmaceutical prices are, of course, centrally determined by the existence of a patent and thus subject to the pricing ceilings regulated by the Patented Medicines Prices Review Board (PMPRB). While the PMPRB assesses comparative therapeutic benefits to establish those pricing ceilings, HTA considers cost-per-QALY as a metric to help decision makers determine affordability and the state's "willingness to pay." Sometimes willingness to pay is influenced by the existence of multiple treatment options, both patented and non-patented. This requires a comparative analysis of cost-effectiveness. The incremental cost-effectiveness ratio (ICER) is the core comparison methodology used in HTA and reflects "the difference in cost between two treatment interventions over the difference in their effect" (Briggs et al. 1997).

There is a vast technical pharmacoeconomic literature on the methodology of QALYs and ICERs and the concepts do not require further elaboration for the present purpose. The key detail to note is they are methodological tools used in health "procurement" decision-making. They are particularly useful when assessing the degree

²⁹⁷ pCODR and its expert committee pERC were originally established independent of CADTH in 2010 by provincial and territorial ministries of health. pCODR was preceded by an Interim Joint Oncology Drug Review (iJODR) established in 2007. CADTH assumed responsibility for pCODR in April of 2014. CADTH Website, "Frequently Asked Questions About pCODR" accessed November 3, 2016 <https://www.cadth.ca/pcodr/faqs>

of clinical improvement and the cost associated with that improvement. The methods are useful for examining expensive and competing health technologies. Pharmaceutical technologies are expensive *ipso facto* that they are subject to trade-related patent protections granted by the state. The removal of compulsory licenses that Canadian payers had relied on heavily between 1969 and 1993 for cost containment purposes also created a policy tool vacuum that HTA began to fill in the 1990s and 2000s. The role of emergent cost-effectiveness institutions as an explicit counterweight to patent reforms under Bills C-22 and C-91 was in fact considered in the health policy literature; however, its prospects for success in this effort were initially mixed and controversial (Lexchin 1997, 75).

Institutional Conversion and Impact

This section discusses how Canada's HTA institutions were repurposed to increasingly mitigate the financial impact of patented pharmaceuticals. This can be viewed as an example of institutional conversion that is a key method of institutional change identified in the historical institutionalism literature (Thelen 2003). The empirical work shows how institutions are converted to more centrally address costs created by patented technologies.

CCOHTA successfully performed its coordination and review mandate for several years and increasingly specialized in how to assess the costs of pharmaceuticals. In 1996 it produced a *Guidance Document for the Costing Process*, and in 1997 produced its *Guidelines for Economic Evaluation of Pharmaceuticals: Canada* (CCOHTA 2001). In 1999, Deputy Ministers of Health again reasserted CCOHTA's role in the health system increasing its annual budget from \$1.7 million to \$4.32 million (CCOHTA 2000). A good

proportion of this increase was directed to CCOHTA's \$500,000 "horizon scanning" program, which "alerts health care managers to issues on emerging technologies" (Ibid). This early warning function bolstered health system managers' planning capacity for future expenditure challenges posed by new technologies.

In March 2002, CCOHTA was selected by Deputy Ministers of Health to house an interim Common Drug Review (CDR) process (CCOHTA 2002). CDR was devised as "a single process for assessing new drugs for potential coverage by publicly funded federal, provincial and territorial drug benefit plans" (CCOHTA 2003). This included a mandate to reduce duplication and "maximize the use of limited resources and expertise" (CCOHTA 2002a). CDR would "critique manufacturer-submitted pharmacoeconomic studies" and employ its new expert committee²⁹⁸ to make formulary listing recommendations to participating drug plans (CCOHTA 2003). It also established common submission requirements for manufacturers to comply with.

In September 2002, Canadian Health Ministers announced CCOHTA would house a permanent CDR process (CCOHTA 2003). Importantly, CCOHTA President Jill M. Sanders tapped Barb Shea to be CDR's first Director. Shea was a provincial drug plan manager with 10-years of experience and responsibility for managing her home province's pharmaceutical budget (CCOHTA 2002a). This is a clear indication of CDR's alignment and orientation in provincial expenditure management. CCOHTA also received a cash injection from the federal government of \$45 million in new funds over five years (CCOHTA 2003).

HTA was becoming a more mainstream part of political discussions. HTA pioneer Renaldo Battista identifies a period of HTA "expansion" where the lexicon of

²⁹⁸ CEDAC referenced above.

HTA intersects with politics: “HTA really becomes part of the official political discourse...politicians will speak of the importance of generating evidence to make better decisions...and at that point there will be increasing demand for a diversity of products” (Battista, public remarks, 2015). Policy makers were demanding more decision-making tools, particularly in the area of pharmaceuticals. Policy maker strategies increasingly reflected their desire to reinforce and bolster HTA institutions.

Reaction to the Common Drug Review was mixed. According to an early independent assessment of the program, manufacturers and patients had immediate concerns about process, transparency, administrative burden, and a lack of patient involvement (EKOS 2005). In response, CCOHTA noted it was exploring options to engage with the public (CCOHTA 2005). A full patient input process was eventually incorporated into the process.²⁹⁹ However, early evaluations of the CDR process suggested a lack of clarity about how patient information was actually used in the decision-making process (SECOR 2013, 18).

CDR and pCODR maintain a recommendation framework that helps to guide the advice of each process’ expert committee. Recommendation options are 1) reimburse, 2) do not reimburse or 3) reimburse with clinical criteria and/or conditions.³⁰⁰ Past frameworks have been similarly structured, but used the terminology of “list,” “do not list,” “list with conditions,” etc. These conditions are very flexible and usually involve clinical parameters, cost improvement criteria, or both clinical and cost criteria. A very common recommendation is for expert committees to recommend a drug for funding but

²⁹⁹ This was incorporated in May 2010.

³⁰⁰ CADTH, “Recommendation Framework for CADTH Common Drug Review and pan-Canadian Oncology Drug Review Programs: Guidance for CADTH’s Drug Expert Committees” accessed September 20, 2016, https://www.cadth.ca/media/cdr/templates/pre-sub-phase/pCODR_CDR_recommendations_framework.pdf

only at a lower price or with improved cost-effectiveness.³⁰¹ This invites negotiation between drug plans and manufacturers. Outright recommendation for funding is fairly uncommon. Generally, a “do not reimburse” (or “do not list” as it has been called in the past) makes it very difficult for a product to be included on a formulary.³⁰²

Drug plan managers are often pharmacists by training but do not have the capacity or expertise (therapeutic, health economics, epidemiology etc.) to evaluate all of the relevant evidence. As such, HTA review is a critical decision-making tool. However, expert analysis is not binding on payers in Canada.³⁰³ They always retain autonomy over listing. Figure 6.2 provides an analysis of CDR recommendations from 2004 to 2011. It stops at 2011 when a new negotiation institution, the pan-Canadian Pharmaceutical Alliance (pCPA), was established.³⁰⁴ This is important to draw a distinction and show that HTA did in fact have a qualitative impact, independent of pCPA negotiations under the new model.³⁰⁵

Figure 6.2: Canadian Drug Expert Committee Recommendations 2004-2011

CDEC Recommendation	Incidence
List	6 (3.6%)
Do not list	77 (45.6%)
List with criteria (i.e. list only as second line treatment; list with improved cost-effectiveness)	62 (36.7 %)
List consistent with therapeutic class (i.e. similar price; same restrictions)	24 (14.2%)
Total products/indications reviewed	169 (100%)

³⁰¹ Data provided below.

³⁰² For many years following the introduction of CDR, a CDR or pCODR “do not list/reimburse” did not necessarily disqualify a drug from provincial funding. Funding could be provided on a province-by-province and product-by-product basis. More recently, since 2011 when provinces entered into joint price negotiations through the pan-Canadian Pharmaceutical Alliance (pCPA), a “do not list” or “do not reimburse” review essentially now disqualifies a drug for coverage under public drug plans. It prevents a drug from even entering the pCPA negotiation process. This is discussed further below.

³⁰³ This is different from other systems that have developed internationally where HTA review decisions are binding on payers. This is discussed further below.

³⁰⁴ The first drug negotiated under the pCPA in 2010 (Solaris™) is not included in the analysis.

³⁰⁵ pCPA’s role is discussed below.

In the pre-PCPA period, around 45% of technologies reviewed by CDR were not recommended for funding.³⁰⁶ For reference, the rate of outright “no” at CDR declined somewhat in the post-pCPA era (Bosnic et al. 2015).³⁰⁷ It is interesting that full recommendations are granted in around 4% of cases. In other words, despite the fact that prices are regulated in Canada by the Patented Medicines Prices Review Board (PMPRB), expert review has determined that only 4% of technologies should be priced at the full price ceiling offered under that regulation. Clinical and economic review mechanisms in Canada yield that around 96% of drugs should either be less expensive than federally regulated pricing levels, or that provincial payers should restrict their use in some way.³⁰⁸ By definition, CDR reviews and net pricing following confidential negotiated rebate payments to government are more restrictive than federal regulatory price controls. *Non-excessive* pricing (PMPRB legislative mandate) is not the same as *affordable* for public health plans (provincial mandate). Federal regulations are still important in promoting price stability and setting maximum ceilings. However, provinces have further constrained net pricing in the public market through HTA-informed negotiations (Morgan, Friesen, Thomson, and Daw 2013b).

While very important in the early years, the PMPRB has evolved to be somewhat less important in the public market, but remains highly important in the private drug market. Much of this decline in relevance to the public market started in 2004 with the

³⁰⁶ Only the most recent CDEC recommendation for each indication was used to arrive at a sample of 169. Several of these initially received a ‘do not list’ that was upgraded upon resubmission. As such, 45.6% is actually a slight underestimate.

³⁰⁷ This rate of “do not list” by CDR declined from 45.6% (2004 - July 2011) to 37% (July 2011 – end of 2014) implying an approximate overall rejection rate of 42% (author calculation). Bosnic et al. (2015) report that 63% (64 of 102) of drugs received a positive or conditional recommendation from July 2011 – end of 2014.

³⁰⁸ For example, more restrictive than the clinical indication as reflected on a Health Canada-approved product monograph.

introduction of the CDR and in 2006 when the province of Ontario introduced confidential negotiated product listing agreements (PLAs) deals. These agreements involved manufacturers negotiating net prices with the province and signing a contract to provide direct rebates to government. Many other provinces followed Ontario with this approach, and eventually it was formalized for all public markets on a national basis through the pCPA (Morgan, Friesen, Thomson, and Daw 2013a).

To show HTA's impact, we must compare the recommendations in Figure 6.2 to actual procurement decisions. Individual procurement decisions appear to be largely consistent with the advice of expert bodies and thus significantly impacted by HTA cost-effectiveness analysis. This has been shown, to some extent, in previous studies of overall percent agreement and percent discordance between Common Drug Review (CDR) recommendations and subsequent provincial listing decisions.³⁰⁹ However, qualitative details about this adoption are required to better understand the mechanics and influence of HTA. This chapter updates analysis in the literature to be current to the introduction of pCPA in 2011, and builds on earlier conclusions with qualitative data.³¹⁰

The conclusion of high consistency is supported by an analysis of individual purchasing decisions where $n=1521$ (169 CDR reviewed products x 9 provinces excluding Québec, given its lack of CDR participation).³¹¹ There is a high consistency of expert review decisions and procurement outcomes. With very few exceptions, negative

³⁰⁹ Gamble et al. (2011) note that “proportion of drugs listed decreased significantly after the introduction of the Common Drug Review for all participating drug plans”

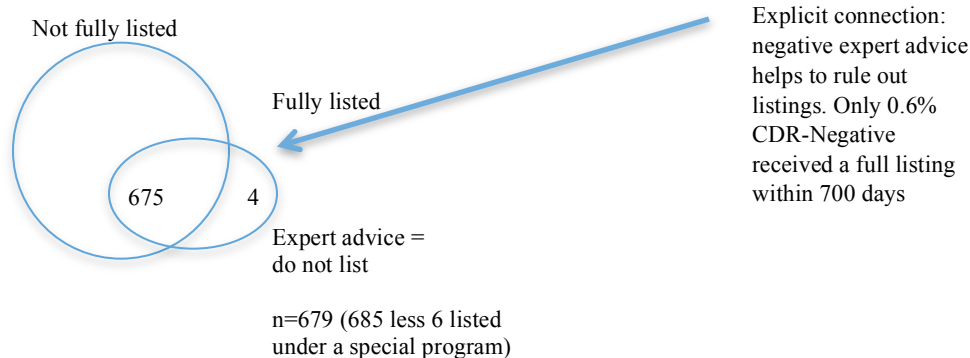
³¹⁰ Rather than using Kappa scores, this analysis looks at the same phenomenon using simple sets as well as qualitative perspectives of decision makers.

³¹¹ These listing decisions are available publicly but are also compiled by IMS Health's FAME™ database and reported in the periodical publication the Provincial Reimbursement Advisor (PRA). This IMS tabulation is highly reliable and has been used for convenience and consistency with studies from the medical and health policy literature. IMS-Brogan, *Provincial Reimbursement Advisor*, Volume 15, Issue 04, 2012.

expert review is a sufficient condition to rule out a full listing. Expert review is a mechanism to rule-out (but not necessarily rule-in) public funding for some technologies.

Of the 169 recommendations 77 were “Do not List.” Four smaller provinces (NS, MB, PE, NL) did not fully list any of these 77 products. Aggregating the data for 9 CDR-participating provinces, produces 693 total purchasing decisions for provinces to make on those 77 “do not list” (DNL) recommendations (77 DNL drugs x 9 provinces). Removing necessary exceptions from the analysis³¹² yields only 4 full listings out of 679 listing decisions (0.6%). Figure 6.3 suggests an explicit connection and substantial role for expert review in justifying no or limited listings.

Figure 6.3: Venn Diagram of CDR-Negative Drugs not Fully Listed in 9 Provinces



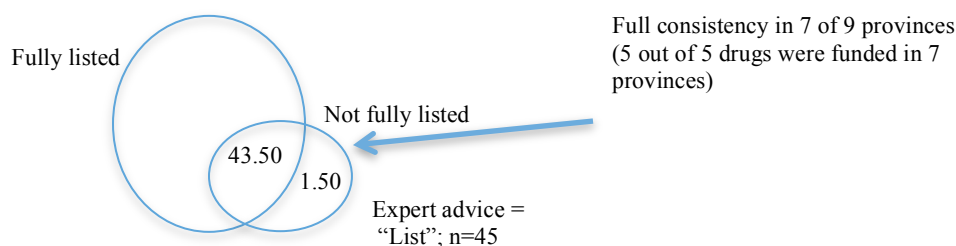
Similarly, CDR-positive advice was a sufficient condition to secure public funding. Of the 5 drugs recommended for funding,³¹³ all five were covered in 7 of 9

³¹² Note: 18/693 (only 2.6%) of those decisions resulted in “full” listings. However, 8 of those listing were delayed by more than 700 days, and thus can hardly count as “full listings.” Removing these from analysis completely yields 10/685 (or 1.5%). Furthermore, 6 of these listings decisions are for only two drugs that were made available on an exceptional basis in many provinces under politically driven special priority health programs. These drugs were exceptions from normal listing process and thus should be removed from analysis. They are diabetes drug Levemir and mental health drug Invega.

³¹³ Advicor™ received a list recommendation from CDEC but is not actively marketed after a company acquisition and thus has been removed from the data. This reflects the difference between the 6

provinces suggesting a near perfect sufficiency condition for those provinces. This relationship is displayed in Figure 6.4. However, the number of cases is small: 5 CDR-positive recommendations times 9 provinces only totals 45 coverage decisions. Based on the circumstance of listing (see footnotes to Figure 6.4), a rough estimate of 43.5 of 45 drugs received listing (96.7%). This suggests a high probability that a CDR “list” recommendation is a sufficient condition for provincial listing (and indeed 100% in 7 of 9 provinces). Only for Manitoba was a CDR positive recommendation not a sufficient condition to gain provincial listing.

Figure 6.4: Venn Diagram of CDR-Positive Drugs Funded in 9 Provinces³¹⁴



However, the picture is more ambiguous in cases where expert review yields less decisive advice, for example, conditional or otherwise modified listing recommendations. In these cases, there is a less clear relationship than for “list” or “do-not-list” cases. For example, of the 86 products that received a CDR-conditional recommendation

CDR-positive recommendations reported in Figure 6.2 and the listing analysis in Figure 6.4 which examines listings for the five CDR-positive drugs (times 9 provinces to total 45).

³¹⁴ Near perfect subset relationship in most provinces for provincial uptake of full list recommendation include: BC: 4.75 out of 5 (Twynsta™ requires special authorization); AB: 5 out of 5; ON: 5 out of 5; NS: 5 out of 5; SK: 5 out of 5; MB 3.75 out of 5 (Twynsta™ not listed; Manitoba has listed one form of Altace, but not its combination product Altace HCT a listing of 0.75 has been used to approximate this situation. <http://web2.gov.mb.ca/laws/regs/pdf/p060-083.13.pdf>; NB 5 out of 5; PE 5 out of 5, however, Yasmin was listed in 2013 so it should be noted this listing was delayed. See: <http://www.gov.pe.ca/photos/original/macmemosept13.pdf>; NL 5 out of 5; Total for all provinces aggregated: 43.5 out of 45 or (96.7%).

(multiplied by 9 participating provinces for a total of 774 subsequent purchasing decisions) fully 24.5% were not listed; 12% were full listings, and 2% were full listings but significantly delayed (>700 days), perhaps due to protracted price negotiations. Provinces followed-up conditional CDR recommendations with conditional listings in 61.5% of those cases.³¹⁵ As such, further qualitative insights are required to fully describe the impact of HTA.

There is also a qualitative impact of conditional recommendations. The role of HTA for these cases is primarily to inform criteria or conditions and inform negotiations. Canadian drug plan managers use clinical conditions and criteria to restrict drug access to a sub-set of the total patient population. Ostensibly, this restricts access to only those patients who will most benefit from the therapy as informed by the clinical evidence. For those technologies that are screened-in for government funding, an important function of HTA is to help restrict criteria or conditions to manage how many patients will have access to them, and under what specific conditions. For example, sometimes HTA recommends that an expensive new drug³¹⁶ be used only if a cheaper alternative is tried first.³¹⁷

³¹⁵ However, the percent of conditional CDR recommendations resulting in “conditional listings” could potentially be as high as 75.5%. This would depend on the extent to which provinces required price concessions via confidential PLAs in exchange for those 14% of cases with “full” listings (61.5% + 14% = 75.5%).

³¹⁶ New drugs are almost always patented and are ‘expensive’ because they are protected by state-granted patent protections.

³¹⁷ Consider the substantially restrictive criteria that go along with the conditional recommendation for *drug x*: “The Canadian Expert Drug Advisory Committee (CEDAC) had previously recommended that [drug x] not be listed. A new randomized controlled trial (RCT) was the basis for the [drug x] resubmission. The committee maintains its prior conclusion that [drug x] has not been proven to be cost-effective in any group of patients but, recognizing the need for treatment alternatives in patients with severe pulmonary hypertension, recommends the following restrictive formulary listing criteria. It is recommended that [drug x] be listed for patients...[who] have both 1. failed to respond to non-prostanoid therapies and; 2. who are not candidates for epoprostenol therapy...” CADTH Website, accessed September 20, 2016,

https://www.cadth.ca/media/cdr/complete/cdr_complete_Remodulin_July20_2006.pdf. Note in this

Both cost criteria *and* clinical criteria are related to expenditure management or ‘affordability.’ The Executive Officer of Canada’s largest provincial drug plan has described the utility of conditional recommendations in expenditure management:

Really helpful information for all of us, and I know a real growing area, is “list with clinical criteria or conditions.” It is providing guidance to the public drug plans, determining who will benefit most from these new therapies, and under which conditions should they be reimbursed for maximum affordability and for positive outcomes for patients. Sometimes it’s very clear; sometimes it’s not (McGurn 2016).³¹⁸

In other words, HTA does not always provide binary yes/no insights, but often allows drug plan managers to narrow and shape coverage criteria to minimize costs and ensure appropriate use.³¹⁹

HTA also informs pricing negotiations between plan managers and manufacturers. A key component of CADTH’s institutional conversion was when provinces made CDR and pCODR reviews mandatory for all new drugs applying for public funding. This was implied as a general norm when establishing CDR in 2004. It was later *formally* entrenched in 2011 when the Council of the Federation’s Health Care Innovation Working Group established pCPA as the common point of negotiation for all

passage the considerable criteria used to limit access to this particular treatment. One of CDEC’s prime considerations was the cost of the drug which ranged from \$18,000 to more than \$70,000 per year depending on the dosing regimen. This new therapy did, however, provide considerable benefits over existing therapies in that it could be administered subcutaneously rather than through a continuous IV infusion through a permanent catheter of the central venous. It would appear that expert review considered this to be a substantial innovation, but not one substantial enough to reward the manufacturer with a full listing at the patented drug’s full price. Most provinces leveraged this expert advice. The drug was only made available as part of a few special access or exceptional drug programs (i.e. not fully listed) and was not reimbursed at all in several major jurisdictions including Ontario, Alberta, Nova Scotia, or Manitoba.

³¹⁸ Suzanne McGurn speaking in her role as Assistant Deputy Minister and Executive Officer, Ontario Public Drug Programs

³¹⁹ This insight is verified by an increase in conditional listing since 2011 (subsequent to the data reflected in Figure 6.2). See Bosnic et al. (2015).

provincial drug plans.³²⁰ This common negotiation mechanism was first referred to a “pan-Canadian purchasing alliance,” was formally named the pan-Canadian Pricing Alliance, and was later formally renamed the pan-Canadian Pharmaceutical Alliance (pCPA). This name change appears to have been an attempt to deemphasize the fact that pCPA’s fundamental role is to negotiate prices and confidential rebates to government. However, this remains an ongoing reality. One study suggests that 80% - 95% of PLAs in Canada remain financial-based rather than health-outcomes-based (Thompson et al., 2016). Politicians who seem to like the procurement metaphor of “bulk-discounts” often inaccurately refer to pCPA as ‘bulk-purchasing’. The process more accurately reflects joint price negotiations.

CADTH review is an essential precursor to public funding in Canada. Technically and legally, there is nothing stopping provincial plans from listing a drug without HTA review or independently of the pCPA. However, provinces have opted to mandate this to maintain integrity of the process. It is mandatory for manufacturers, but provinces can opt-in or opt-out on a product-specific basis.³²¹ As a ‘procurement’ assistance mechanism, HTA review really informs the starting parameters for these pricing negotiations. With a few exceptions including re-negotiations, HTA review and pCPA

³²⁰ Council of the Federation, “Premiers Protecting Canada’s Health Care Systems” August 6, 2010 press release, accessed September 14, 2016, <http://www.conseildelafederation.ca/en/latest-news/17-2010/153-premiers-protecting-canada-s-health-care-systems>

³²¹ “In general, all new drugs approved for use by Health Canada are then submitted by the drug manufacturer for review under the national Common Drug Review (CDR) process for non-oncology drugs and under Pan-Canadian Oncology Drug Review (pCODR) for oncology drugs... Once CDR or pCODR releases its final recommendation, the Pan-Canadian Pricing Alliance (pCPA) decides whether joint pan-Canadian negotiations will occur for the drug product. If the decision is to move forward with negotiations through the pCPA, one jurisdiction will assume the lead and confirm with the manufacturer which jurisdictions are participating... [it is] up to each participating jurisdiction to make their final decision on funding the drug product through their own public drug plan and enter into a jurisdiction-specific product listing agreement with the manufacturer.” Pan-Canadian Pharmaceutical Alliance Website, accessed September 5, 2016, http://www.canadapremiers.ca/phocadownload/pcpa/scope_of_pcpa_process_sept_2014.pdf

apply to all new patented drugs seeking funding. pCPA has become the most important venue for the negotiation of pricing and has helped to further entrench the important role of CADTH as a mandatory review prior to pCPA negotiations.³²² pCPA also maintains a separate price-setting process for generics that does not involve an HTA review and tiers pricing by product (ranging from 75% to 18% of originator brand product) according to the number of generic competitors on the market.³²³

HTA is most routinely applied at product launch. As such, drug plan managers see a clear future role for HTA to evaluate drugs currently on the market. These drugs may not have received the same cost-effectiveness scrutiny at launch or may not have performed as effectively in real-world use as anticipated by the initial clinical assessments (McGurn 2015).³²⁴ As HTA evolved in Canada, its role and importance to decision making has only grown. It continues to adapt to decision-maker needs for ‘ongoing’ assessments, not just at product launch, but also to facilitate decommissioning or ‘disinvestment’ in technologies. The term Health Technology Management—as opposed to Health Technology Assessment—has been used to describe its future role.³²⁵ CADTH already does some of this type of work through its Therapeutic Review program that comparatively evaluates full classes of drugs already on the market for “optimal use”

³²² While tremendously important for pricing, it should be noted that the introduction of pCPA itself has not had a significant impact on the overall *proportion* of new drugs listed across provincial jurisdictions (Milliken et al. 2015).

³²³ The lower 18% of the originator brand price threshold is applied for at least 18 high-volume generic drugs; Pan-Canadian Generics: Pan-Canadian Tiered Pricing Framework – Government of Saskatchewan website, accessed September 5, 2016, <http://formulary.drugplan.health.gov.sk.ca/PanCanadian.aspx>

³²⁴ Speaking in her role as Assistant Deputy Minister and Executive Officer, Ontario Public Drug Programs, Suzanne McGurn made the following comments: “How do we build on the success and learnings that we’ve had in this era of evidence-driven decision-making that CADTH has been such a significant contributor to, how do we actually start evolving that work to support decisions that aren’t just at the front end...” (McGurn 2016).

³²⁵ Brian O’Rourke, “Health Technology Management,” 88-90, CADTH website accessed November 28, 2016, <https://www.cadth.ca/sites/default/files/events/PM%20Session%20-%20Drug%20Portfolio%20Info%20Sess%20-%20Oct%2026%202016%20-%20FINAL.pdf>

in practice (see Figure 6.7). Where Health Technology Management (HTM) seems to be most promising, however, is in a new initiative announced in 2017 called the “Cancer Drug Sustainability Initiative”. This effort is being led by the Canadian Association of Provincial Cancer Agencies (CAPCA) and involves coordination of various system players including CADTH and the pCPA. Health Technology Management efforts including the CAPCA drug sustainability initiative can be considered a unique and emerging institutional “re-assessment” layer.

In addition to these formal institutional constraints on the pricing and availability of patented product there is also a *de facto* constraint on overall effective patent life from a time perspective. This varies depending on HTA and negotiation agency workload. CDR review time target is 180 calendar days.³²⁶ This is one component of overall “time to provincial listings” for which estimates range but has been assessed by IMS-Health and the brand industry association at 449 calendar days.³²⁷ The extent of time to listing and “effective patent life” are contested between brand and generic industry associations, but there can be no doubt that the layering of HTA and negotiation institutions adds significant time to the product review process and thus constrain effective patent life. The magnitude of this constraint will vary by product, provincial jurisdiction, and has fluctuated over time.

³²⁶ “From the time that an application is accepted for review to the date of issuing an embargoed Canadian Drug Expert Committee (CDEC) recommendation.” CDR Process in Brief, accessed April 12, 2017, <https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/common-drug-review-submissions/process-in-brief>

³²⁷ “Across provinces comprising 80% of the eligible national public drug plan population.” Brad Millson, Sherri Thiele, Yvonne Zhang, Wendy Dobson-Belair, and Brett Skinner, “Access to New Medicines in Public Drug Plans,” 2016 Annual Report, Innovative Medicines Canada, accessed April 12, 2017, http://innovativemedicines.ca/wp-content/uploads/2016/05/20160524_Access_to_Medicines_Report_EN_Web.pdf. It should be noted that delays can be caused by many factors and measurement of time-to-listing is impacted by methodology (e.g. 80% population coverage versus other potential metrics).

Canadian policy makers adopted the principles of evidence-based medicine and actively supported the development of HTA. They repurposed an existing institution to help manage cost concerns related to patented pharmaceuticals. Provincial policy makers have since confirmed the important role, and potential future expansion of HTA, in managing the pipeline of new pharmaceuticals coming to Canada from international firms (Bell 2016).³²⁸

The US drug industry takes an alternative perspective and views Canadian institutions as rationing bodies. US companies have taken aim at these practices, and general pricing levels in countries that employ HTA-informed negotiations in comparison to the US, where prices are much higher:

Most of these countries, if you look at Canada, if you look at Australia, if you look at New Zealand, all highly developed countries, all freeriding on inventions in the United States. If you look at access for their population– I don't have exact numbers here, but I think if you say there were 100 new products authorized in the United States, Australia and New Zealand, their population only has access to 30% of them. The UK, they have access to 47% of them, normally, two to three years later than the US. Their citizens are not getting quality healthcare...Canada is cheaper because of rations. And Canada is cheaper because it can, because it freerides off American innovation. In our industry, let me be very clear here, we have sunk all the money up front... What you're paying for is all of that clinical trial, all of that knowledge, all of that experimentation, which tells you [the] pill will do what it will do...And so, once you've done all that work, you're very subject to commercial blackmail [by governments]... You cannot negotiate with governments.³²⁹

³²⁸ Ontario Deputy Minister of Health, Dr. Bob Bell commented publicly on this in 2016: “Where could CADTH play its maximum role? And I’m speaking now from the Deputy Ministers’ table, what help do we need?... There’s no question that for many provinces, expanded effort in health technology assessment is essential. But I guess what I would say is that we in Canada look off on our shores and we see these multiple pipelines coming into the country... is it possible that we can look at CADTH for health technology, along with partners in various other provinces that have experience in HTA, especially in pharmaceuticals, where I think the entire country accepts that [CADTH] has primacy in both oncology and non-oncology drug value assessment... Could we say that the first stop shop, for anybody who wants to bring any new product, especially any new pharmaceutical to Canada, would be an evidence review by CADTH?..” (Bell 2016).

³²⁹ Ian Read, Pfizer CEO, Statement at the US National Press Club, March 23, 2017, accessed April 5, 2017 http://www.press.org/sites/default/files/20170323_read.pdf

This statement is *somewhat* overstated as there are sources of leverage on both sides of a negotiation. At least in Canada, institutions *do* attempt to base decisions on the best available evidence. These statements are closely aligned with similar statements from President Trump who has criticized US drug prices, but intends to simultaneously address the pricing and investment imbalances: “Foreign countries must pay a fair share for drug development costs... We're going to end global freeloading.”³³⁰

The point is that Canadian HTA and negotiation institutions are carefully watched, scrutinized, engaged, and sometimes challenged by US industry. In the early years (1997-1998), CCOHTA faced an injunction lawsuit from an American company regarding one of its drug reviews for being “negligently misleading” and containing “negligent misstatements” (Skolnick 1998, 283-4). The court denied the injunction and affirmed that CCOHTA had taken steps to ensure scientific accuracy, noting that an injunction would “virtually render the defendant [CCOHTA] useless” within the Canadian system (Ibid). While successful, the legal defence alone cost CCOHTA 13% of its annual budget (Ibid).

US government opposition to HTA and negotiation institutions is perhaps less blatant than USTR activity on IP and the promise doctrine (Chapter 5). Part of the reason is that HTA has gained broad legitimacy as an evidence-based approach to decision making, and companies implicitly acknowledge the reality that HTA in many countries is

³³⁰ Roberta Rampton and Deena Beasley, “Trump pushes drug makers for lower prices, more U.S. production” *Reuters* January 31, 2017, accessed April 5, 2016, <http://www.reuters.com/article/us-usa-trump-pharmaceuticals-novartis-idUSKBN15F13K>. While the diagnosis of “freeloading” is consistent between these two perspectives, the *prognosis* would seem somewhat different. The CEO perspective seems to suggest that that government institutions will continue to have considerable leverage. It is unclear what specific measures President Trump has in mind.

here to stay. However, direct opposition from large US corporations is clearly present.³³¹ US government-level debates have focused on the potential use of Canadian and UK-style HTA and negotiation approaches in US market. The polarization of this debate was most prominent in the 2010 *Affordable Care Act* discussions (see below). The potential use of cost-effectiveness research remains a point of ongoing debate among various US stakeholders (Concannon et al. 2015, 16).

Though these mechanisms have not yet been widely adopted in the US, reviews in small countries like Canada can have reach beyond borders and are closely watched by US corporations. US company regulatory filings with the Securities and Exchange Commission (SEC) have noted the risk posed by negative HTA reviews:

HTA organizations, such as NICE in the UK and the Canadian Agency for Drugs and Technologies in Health, make reimbursement recommendations to payers in their jurisdictions based on the clinical effectiveness, cost-effectiveness and service impact of new, emerging and existing medicines and treatments. Any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could materially and adversely affect our product sales, business and operating results. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price for our common stock.³³²

Despite having considerable size and ability to gain support within the US political system, the power of the US pharmaceutical industry to drive favourable outcomes for patented products internationally is often exaggerated. Comparatively minuscule state HTA institutions with paltry budgets can significantly impact US companies with billions in resources. Market power cannot fully explain these dynamics and the institutional

³³¹ This opposition is not universal and many companies work collaboratively with HTA organizations.

³³² Amgen Inc. 2012 Form 10-K “Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934,” accessed April 20, 2017, <https://www.sec.gov/Archives/edgar/data/318154/000144530513000364/amgn-12312012x10k.htm>

sources of power that shape the broader environment for patented products. Market power may be a useful incentive to secure adoption of an international standard, but has limited broader utility in explaining the design and real-world role of regulatory standards.

In summary, while HTA institutions were established separately from Canada's trade diplomacy, the evolution of HTA was a key policy feedback. It was an additional institution layered on top of the regulatory price control institution implemented and enhanced under Canada's trade deals. This institutional layering and conversion constitutes a meaningful mitigation to the trade-related IP regime and calls into question the analytical utility of a strict market power account.

How Private Drug Insurers Attempt to Leverage Public Institutions

This section provides a concise within-case comparison to show the significance of public institutions. Canada's private drug market has not yet developed a comparable institutional capacity. It shows that the private market has actively attempted to leverage public institutions to contain its own cost exposure.³³³ Private payers look to the future with particular concern over cost growth. They have: advocated for a more activist Patented Medicines Prices Review Board to drive down prices and a role in the institution's governance; adopted CADTH's HTA reviews in some cases; and have sought access to negotiated prices through participation in public plan negotiation mechanisms.

³³³ There were several years of pharmaceutical expenditure expansion in Canada following TRIPS. More recently, public sector cost-containment and a "patent cliff" of patent expiries for several "blockbuster" products has provided several years of modest pharmaceutical growth at or below 2% annually. CIHI, National Health Expenditure Trends, 1975 to 2015, data tables, accessed September 22, 2016, https://www.cihi.ca/sites/default/files/document/nhex_2015_datatables_en.zip

Prescription drug spending in Canada is around \$29.2 billion (around 13.3% of total Health Spending in Canada) and is split between public, private and out-of-pocket sources.³³⁴ Public drug programs typically cover elderly adults and those on social assistance. Provinces also provide catastrophic drug programs that range somewhat but provide coverage when patients' drug expenditures exceed a certain percentage of household income, usually in the range of 2-5% (Phillips 2016).³³⁵ Public spending on prescription drugs in Canada is approximately \$12.6 billion (2015) and constitutes around 43% of prescription drug spending.³³⁶

Private employer-based drug insurance plans are usually offered by one of 4 or 5 major insurers. Prescription drugs reimbursed by private plans were \$10.2 billion in 2015 and constitute around 35% of prescription drug spending. Direct out-of-pocket spending by patients on prescription drugs in Canada was about \$6.4 billion in 2015 and constitutes approximately 22% of total prescription drug spending.³³⁷ Of the \$29.2 billion in total prescription drug sales reported by CIHI, only 52% or \$15.2 billion are for patented drug costs at the factory gate (ex-factory sales).³³⁸

Figure 6.5 shows a comparative distribution of Canadian prescription drug spending for 1992 pre-NAFTA/TRIPS as compared to 2015. It shows a substantial

³³⁴ For an analysis related to patented drugs, it is important to differentiate prescription drug spending from total drug spending which includes over-the-counter and personal health supplies. Data source: CIHI, National Health Expenditure Trends, 1975 to 2015, data tables, accessed September 22, 2016, https://www.cihi.ca/sites/default/files/document/nhex_2015_datatables_en.zip

³³⁵ Some provinces provide universal coverage (e.g. Québec and New Brunswick) and others provide a range of catastrophic drug policies. For a good overview of the fragmented Canadian market for pharmaceuticals and the range of provincial coverage frameworks, see Canada's Library of Parliament publication: Phillips (2016).

³³⁶ At time of writing these were the most recent data available from the Canadian Institute for Health Information (CIHI), Canada's official statistician for the health sector. Per CIHI publication practice, all figures for 2015 herein are forecast. Calculation of percentage share are the author's. CIHI, National Health Expenditure Trends, 1975 to 2015, data tables, accessed September 22, 2016, https://www.cihi.ca/sites/default/files/document/nhex_2015_datatables_en.zip

³³⁷ Ibid.

³³⁸ PMPRB Annual Report 2015.

decrease in the percent share of the public prescription market (48% to 43%), and a commensurate *increase* in the total share of the private sector. Public and private plan dynamics are somewhat different and there may be multiple causes for these trends. However, active plan management in the public market is undoubtedly a major factor.

Figure 6.5: Public, Private, and Out-of-Pocket Share of Total Prescription Drug Spending

	Public Plans (% of total prescription drugs)	Private Plans (% of total prescription drugs)	Out-of- Pocket (% of total Prescription drugs)
1992	48%	32%	20%
2015	43%	35%	22%

Figure 6.6: Cumulative Increase in Annual Prescription Drug Spending

	Public Plans	Private Plans	Out-of- Pocket
2004 - 2015	52%	64%	90%

Figure 6.6 shows actual expenditure growth since the introduction of the Common Drug Review (CDR) in 2004. Each category has predictably increased considerably with the expansion of patent protections, drug volume, and proliferation of available technologies. However, the public institutions seem to have managed this growth better than the private sector.

Perhaps most pressing for the private sector is not its past capacity to constrain spending but what it sees as *future* challenges as new “specialty medicines”³³⁹ come to

³³⁹ Specialty drugs are “medications used to treat chronic, complex conditions such as rheumatoid arthritis, multiple sclerosis and cancer. Specialty drugs are usually costly, require special storage and handling, need intensive clinical monitoring and require frequent dosing adjustment.” It was noted in 2015 that there were 7000 potential drugs under development, most of which were specialty drugs, and that by 2020 42% of private market drug spending will be in area. Express Scripts Canada, Drug Trend Report

market. Insurance models are apparently unprepared to weather future shocks. By the private insurance sector's own admission, it has faced considerable challenges managing exposure to high-cost drugs and looks to the future with considerable concern:

Rising drug costs, particularly related to the increasing incidence of rare but very high cost drugs, undermines the ability of employers to continue to offer drug coverage benefits to employees... Any long-term solution to these challenges will require both public and private payers to make adjustments to their programs and to work more collaboratively going forward (CLHIA 2012).

Here the private sector is clearly aiming to align itself with the public institutions. This concern over future costs is disputed. The brand pharmaceutical industry association Rx&D³⁴⁰ noted in an analytical response to the Canadian Life and Health Insurance Association (CLHIA) that private costs “will remain sustainable into the foreseeable future” (Rx&D 2013).³⁴¹ However, there can be no doubt that the private market has not contained costs and future exposure to the *same extent* that public institutions have. The public sector has institutional tools in place that can evolve to better deal with future expenditure challenges in an evidence-based manner.

To address this perceived policy gap, the private insurance sector has attempted to leverage public institutional capacity in three central ways. First, it has lobbied Canadian policy makers to make more aggressive use of PMPRB's price control powers (CLHIA 2016; CLHIA 2012). In particular, it requested that the PMPRB be tasked “to achieve the lowest possible prices” as opposed to its legislated mandate to ensure that patented prices are not “excessive.” The insurance industry has proposed that the PMPRB's basket of

2015, accessed December 2, 2016, <http://www.express-scripts.ca/sites/default/files/2015-Drug-Trend-Report.pdf>

³⁴⁰ This association is now called Innovative Medicines Canada.

³⁴¹ It should be noted that this analysis only projected 2012- 2017 which is a reasonable time period for a market that can change quickly with the introduction of new technologies.

international reference countries should be amended to include lower cost OECD jurisdictions for regulatory price comparison purposes. Also, it is suggested that the frequency of product review be increased, to every 5 years, or when there are “material changes in volume” of use for a particular drug. In perhaps the most direct signal of the private insurers’ desire to harness the PMPRB’s power, it has recommended that the five-member board “be required to include private insurer representation” (CLHIA 2012). This would present a clear conflict of interest, but it is a very interesting indication of the private sector’s desire to leverage public institutions.

Secondly, individual insurers have actively leveraged CADTH’s HTA review processes. In 2011, former Ontario drug plan manager Helen Stevenson established the ‘Reformulary Group,’ a company that essentially tried to apply elements of public drug plan management and HTA methodology to private plans through an “evidence-based formulary.”³⁴² Stevenson established her own expert committee similar to CADTH’s and attracted a few insurer clients including Sun Life Financial. This appears to be the first foray of Canada’s private market into public-style reimbursement mechanisms. However, after 5 years in operation Reformulary had only attracted insurance plans totaling 110,000 lives as of September 2016.³⁴³

Other insurers have *directly* adopted CADTH reviews, making them a formal part of some private plan reimbursement processes. In 2015, Canada’s largest private drug

³⁴² Reformulary Website, accessed September 22, 2016, http://www.reformulary.com/index_en.php?page=our_team; Sun Life Financial, 2011, “Sun Life and Reformulary Group announce strategic alliance to help lower drug costs for employers” Press release December 15, 2011, accessed September 22, 2016, <http://www.newswire.ca/fr/news-releases/sun-life-and-reformulary-group-announce-strategic-alliance-to-help-lower-drug-costs-for-employers-509271751.html>

³⁴³ Reformulary Website, accessed September 22, 2016, http://www.reformulary.com/index_en.php

insurer Manulife instituted the “Manulife Drug Watch” program. According to its promotional material directed to plan sponsors (employers):

Drugs expected to impose a considerable financial cost on...drug plan[s] will be placed On Watch and subjected to further review before they can be considered for addition to [the] plan...Manulife will base its evaluations on the publicly available information from the Canadian Agency for Drugs and Technologies in Health (CADTH).³⁴⁴

Like the public system, this leverages negotiations with manufacturers based on Manulife’s review of CADTH assessments.³⁴⁵ There is no available data on *exactly* how CADTH information is used in this review process and it remains to be seen how closely Manulife drug plans will harmonize with public plans. Harmonizing coverage standards with public plans seems to be a long-term goal of the private sector and it has called for public and private systems to jointly establish a common national minimum formulary (CLHIA 2012, 28).

Third, the private sector has sought access to and participation in confidential pan-Canadian Pharmaceutical Alliance (pCPA) product listing agreement negotiations that make considerable use of CADTH’s HTA assessments. The private insurance sector is opposed to the public insurance sector’s use of *confidential* PLAs that do not benefit private plans and thus ultimately entail differential net pricing in Canada:

through the Council of the Federation's pan-Canadian bulk buying alliance, the provinces have collaborated on negotiating PLAs...[the PLA] process disadvantages private plans and those paying out-of-pocket by ultimately keeping prices high for those purchasing their drug privately...to the degree that PLAs continue to be used by the provinces in Canada, we believe that they should equally benefit private payers and Canadians paying out-of-pocket (CLHIA 2012).

³⁴⁴ Manulife Website, accessed September 22, 2016, www.manulife.ca.

³⁴⁵ Introducing Manulife DrugWatch, accessed September 22, 2016, http://pointbreakcg.com/wp-content/uploads/2015/09/DrugWatch-Brochure_GC2690-E.pdf

It is not at all clear how public PLAs “keep” private insurer prices high. Sophisticated insurance industry transnational corporations (TNCs) are more than capable of negotiating their own deals with pharmaceutical TNCs, and need not rely on public officials to secure lower prices. However, out-of-pocket patients would seem to be disadvantaged in a system where major public and private payers can negotiate prices and rebates to list prices.³⁴⁶ Unfortunately, there is no good data on the extent of those uninsured for drug coverage in Canada. Large provinces such as Québec have universal coverage and an individual insurance mandate. Other provinces have catastrophic drug programs (Phillips 2016).

The private insurance industry’s lobbying (and the lobbying of other stakeholders) has fallen on sympathetic ears in the Trudeau administration that took power in 2015. In a 2016 speech, the Federal Health Minister signalled she will move forward with many of the same reforms advocated by the insurance industry including 1) PMPRB reform, specifically referencing the influence of high US pricing in its international benchmarking;³⁴⁷ 2) establishing a common national formulary; and 3) even raising the prospect of private plan inclusion in confidential pCPA negotiations. The federal

³⁴⁶ One prominent patient organization has acknowledged this: “The question of different pricing levels for public payers, private/corporate payers, and individual patients is important and warrants further examination in light of current system realities. Currently, both private and public payers have tools available to negotiate prices but individual payers do not. This is a hardship for individuals who don’t have bulk buying power and could be viewed as discriminatory.” Best Medicines Coalition, Submission to the PMPRB, October 2016, accessed January 30, 2017, http://www.pmprb-cepmb.gc.ca/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Best_Medicines_Coalition_Oct_2016.pdf.

³⁴⁷ “We also need to review, and I think this is a very exciting area, the role of the regulatory body, whose job it is to protect Canadians from excessive brand name drug prices. Right now you may know that the Patented Medicines Prices Review Board is required to use as benchmarks for deciding the right price...they are compared against some of the highest cost manufacturing jurisdictions in the world, including the United States” Hon. Jane Philpott Speech, September 29, 2016, Ottawa.

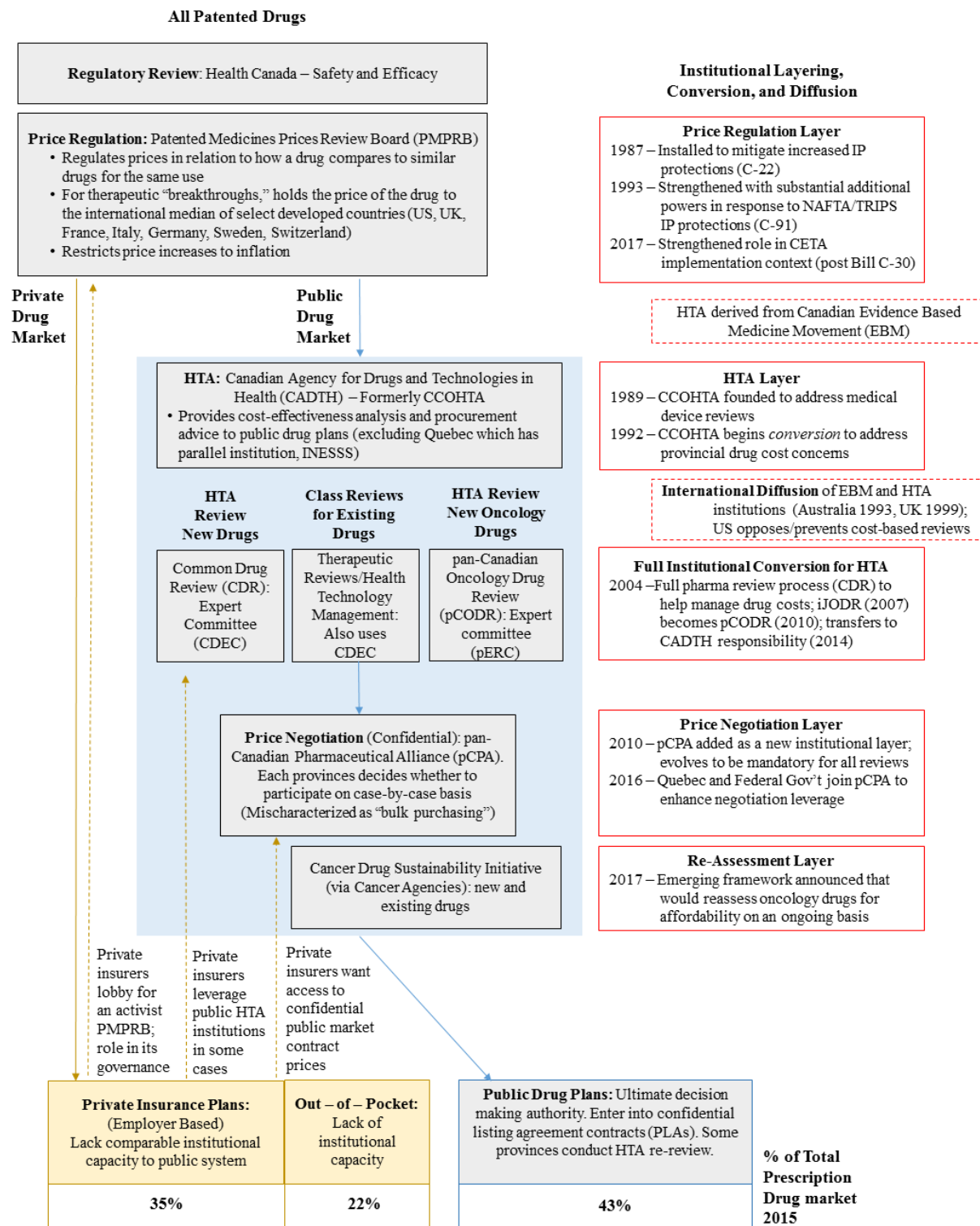
government itself only entered pCPA months earlier in 2016.³⁴⁸ While the private insurance industry struggled for many years with lower institutional capacity, it now seems poised to better leverage public institutions.

The prospect of PMPRB reform was also raised by the Board itself in 2014 when it embarked on a year-long strategic planning process “for the next quarter century” (PMPRB 2015c). The PMPRB recognized that the implementation of the Canada-EU Comprehensive Economic and Trade Agreement (CETA) would require changes to the *Patent Act*. The Board Chair used this as an opportunity to spark a process of renewal that would see the PMPRB “reaffirm its consumer protection origins” (Ibid). As with past trade treaty implementations, Canadian institutions seem poised to assert space for themselves within the policy process. Many of the private insurance industry’s priorities were also reflected in the PMPRB’s early response to the evolving international IP environment. This was captured in a June 2016 discussion paper that kicked off a PMPRB Guidelines reform process. Some of the many issues flagged for potential reform by the PMPRB include: 1) price discrimination between payer types (i.e. public versus private) due to public PLAs; 2) price ceilings revised with the passage of time (i.e. regular price re-benchmarking or on launch of new therapeutic indications); 3) issues related to pricing tests and which PMPRB7 international comparator countries should set Canadian patented price ceilings;³⁴⁹ and 4) the important new role that CADTH plays in pharmaceutical cost-effectiveness review based on therapeutic merits (PMPRB 2016).

³⁴⁸ “I hope to explore with the provinces and territories ways to further look at the advantages of bulk-buying and joint price negotiations which we are now doing across the country, saving now over \$700 million a year, and the possibility of expanding that bulk-purchasing... negotiation to the private insurance plans as well” Hon. Jane Philpott Speech, September 29, 2016, Ottawa.

³⁴⁹ The PMPRB made explicit reference to how US prices “skew the median [price] calculation”

Figure 6.7: Institutional Layering and Capacity in the Canadian Public Market as Compared to the Private Market



In summary, the private insurance sector, the PMPRB, and the federal Minister of Health all seem to be in general alignment on these points. The private market seems poised to more fully leverage public institutions in the future. Figure 6.7 shows the intricate layering and conversion for the institutions discussed to this point.

International Diffusion of Canadian Ideas and Cost-Effectiveness Institutions

This section discusses the international diffusion of Canadian ideas and the establishment of comparable institutions internationally. As identified above, evidence of Canada's leadership on an international diffusion of evidence based medicine and HTA for pharmaceuticals would tend to call into question a market power hypothesis and lend support to an historical institutionalism hypothesis. Indeed, much of the OECD now uses some form of HTA assessment as a basis for public decision-making on patented pharmaceuticals (OECD 2008). Canada was a pioneer in evidence-based medicine and cost-effectiveness reviews that diffused rapidly across the world through international epistemic cooperation (Culyer 2013; Battista, public remarks, 2015; Hailey and Menon 1999; Sackett 2015). Australia was also an early adopter in 1992-93 and was the first country to institute a mandatory HTA review for all new drugs considered for formulary listing (Government of Australia 2009, 47). This was a mandatory process for all manufacturer applications for funding, but like Canada, HTA decisions were non-binding on government. As HTA spread internationally its methodologies, definitions of costs, benefits, value,³⁵⁰ institutional structure, processes, outputs and proximity to funding decision makers all varied to some extent. This examination illustrates an alternative

³⁵⁰ See Valérie Paris and Annalisa Belloni, "Value in Pharmaceutical Pricing," *OECD Health Working Papers*, No. 63, (Paris, OECD Publishing, 2013), accessed November 10, 2013, <http://dx.doi.org/10.1787/5k43jc9v6knx-en>; Sorenson, Drummond and Kanavos (2008).

model to the dominant image of regulatory standard-making as a function of solely power. Standards arise in different path dependent ways and even small powers can have significant influence through their ideas and through cooperation.

Sometimes HTA analysis relates strictly to comparative cost-effectiveness. Other countries such as Sweden decided not to make coverage decisions based on specific cost-per-QALY thresholds but considered specific government budget impact assessments in the decision making process (WHO 2015, 65; OECD 2008).³⁵¹ The UK's National Institute of Health and Clinical Excellence (NICE) was established in 1999 to conduct HTA reviews, determine product availability and inform pricing within the National Health Service (NHS). NICE functions internal to the government National Health Service (NHS). Expert decisions are largely binding within the system. For example, if a patented technology is recommended by NICE, NHS centers across the country must provide it (PPRI 2015).

Other international HTA bodies are not as operationally close to government nor are their decisions binding on government payers. What unifies international HTA processes is their core function: HTA mediates demand for health technologies via expert or scientific analysis. Cost-effectiveness is most often an explicit mandate for these organizations and governments rely on their advice to mediate requests for funding from both manufacturers and the public.

Dr. Tony Culyer was the inaugural Vice-Chair of NICE and an important figure in the internationalization of HTA. For several years, he chaired NICE's International outreach activities and later was a member of CADTH's Board. At a public presentation

³⁵¹ Canadian provinces also make extensive use of budget impact assessments submitted by manufacturers.

in 2013, Culyer commented on the centrality of Canadian ideas and methodologies to the development of NICE, which quickly grew in capacity and prestige to become the preeminent HTA body internationally:

NICE didn't pioneer tremendously much, I don't think, the methodology of HTA...CADTH's predecessor, CCOHTA was there before NICE was ever invented, and in the early days we relied quite heavily on the experience and the advice, and the guidance that the Canadians had invented...Just as Canada invented evidence-based medicine (Culyer 2013).³⁵²

Canada was clearly a catalyst for international policy learning. EBM principles and HTA methodologies seem to have diffused organically through knowledge sharing and international epistemic cooperation. Canada was not alone in this effort and was not even the first globally to institute HTA for devices as both the US Congress and Sweden had earlier HTA mechanisms in the 1980s (Banta and Jonsson 2009). However, cost-based HTA was not applied to drugs in Sweden that were negotiated with its regulatory drug Board, established as an independent body in 1990 (Jonsson and Banta 1995, 221). Canada played a key role in the development of EBM and the international diffusion of cost-based pharmaceutical HTAs. One 1997 assessment acknowledged the Canadian and Australian system of cost-based HTA as leaders in comparison to those in Europe (Drummond, Jönsson, and Rutten 1997).

Throughout CCOHTA's (now CADTH's) existence it has maintained strong linkages with similar bodies developing internationally under various knowledge sharing fora on assessment and methodology (CCOHTA 2003).³⁵³ For example, CCOHTA was

³⁵² From its creation in 1999 until 2003, Culyer was Vice-Chair of the National Institute for Health and Clinical Excellence (NICE); he also served as Chair of NICE International and was a member of CADTH's Board.

³⁵³ International Information sharing fora include the International Network of Agencies for Health Technology Assessment (INAHTA), a network of 52 global HTA agencies; the global scientific and

fundamental to initiating and housing the first secretariat for the primary international HTA knowledge-sharing forum, the International Network of Agencies for Health Technology Assessment (INAHTA) (Hailey and Menon 1999). This forum and others such as Health Technology Assessment International (HTAi) were preceded by foundational epistemic societies and conferences within which Canadian academics also played leadership roles (Banta, Jonsson, and Childs 2009).

Clearly there were normative, functional, and cooperative elements to this diffusion. The idea that medical practice should be based on the best available evidence is a critical norm that had achieved wide intuitive appeal. This spread through international epistemic community dialogue. According to one student of international HTA networking efforts, an important component of INAHTA's success was "routine interaction of its members with public sector decision makers" (Hailey 2009, 26). This is not surprising given that HTA provided many useful tools for improving health outcomes as well as managing government costs. By contrast, earlier networking initiatives ran into resource issues and, while foundational, were not sustained as ongoing institutions (Banta, Jonsson, and Childs 2009). It would seem that national institutional support from government decision makers was a key success factor.

This makes sense given that advancements in medical science and the proliferation of health technologies posed both opportunities and challenges to public managers. TRIPS' patent protections ensured that those innovations would be rewarded

professional society Health Technology Assessment International (*HTAi*) as well as the *World Health Organization Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies* and its networking and information-sharing initiative *Pharmaceutical Pricing and Reimbursement Information (PPRI)*. CCOHTA (now CADTH) is particularly active within INAHTA. For example, CADTH's CEO was also Chair of the INAHTA Board in 2016.

but also would come at a financial cost. HTA helped to moderate the resulting increase in demand for resources.

While developed in large part in Canada, the adoption of HTA was really a country-specific process that was greatly influenced by established national health systems, institutions, and power hierarchies. One detailed assessment of HTA and reimbursement mechanisms in Europe notes the context-specific nature of its adoption:

As one component in the broader health-care decision-making process, HTA programmes typically reflect the current national policy landscape such as the need to contain costs or improve access to a given intervention or service... Almost all [European] countries require assessments to ascertain reimbursement status, although they place differing importance on the economic evidence...some reimbursement committees may require assessments only for patented drugs and new indications... Overall, health economic evidence appears to have the most impact for decisions on drugs with broad use (thus, significant potential budget impact) and when [cost-effectiveness] varies by indication or patient sub population (Sorenson, Drummond and Kanavos 2008, 12, 27).

In other words, HTA is used in different ways according to local preferences. The degree to which cost-effectiveness analysis is used for cost-containment on patented drugs reflects domestic decision making processes and circumstances.

This new, more technocratic and arms-length decision making framework challenges existing hierarchies and places experts in a position of considerable power. Naturally, different countries will respond to this in different ways depending on local political and institutional factors. Consider Culyer's candid remarks based on his experience in helping the UK install a Canadian-inspired HTA framework:

How do you get an organization that in principle, if it's not very careful, could challenge and threaten pretty well every significant player in the health care...scene? It looks like it might be a threat to patients, because it gets set up as a kind of cost-constraining organization. It threatens the professionals because they don't like

being told what to do. It seems to infringe clinical freedoms, and so on. It certainly looks like a threat to manufacturers who don't really want their stuff scrutinized to that extent. It threatens politicians in a way, because some of the judgments that organizations like CADTH and NICE make are essentially statements of social policy, and politicians might think those decisions are more appropriately taken elsewhere, than at arm's length (Culyer 2013).

Culyer's perspectives cut to the heart of the politics of these institutions. Despite frequently including mechanisms for patient and clinician input and participation, HTA is fundamentally a methodological assertion of social policy.

The inherently political nature of HTA entailed that its institutional adoption in each country reflected the existing system to a considerable extent. In Canada's case, political decision-making was not *usurped* as the HTA process operates separately from provincial reimbursement decisions. Provincial governments wanted to maintain full authority over formulary listing decisions.

Some countries have made more aggressive use of HTA review in their own drug listing processes. For example, New Zealand has used HTA as a basis for other policy tools such as reference-based pricing (RBP) and used sole-source tendering for generics following patent expiry. Reference based pricing essentially forces all prices in a therapeutic class to the lowest price in that class.³⁵⁴ These can be organized into sub-groups of the class, based on the level of therapeutic value. Sole-source tendering is applied when governments actually purchase technologies through a competitive bidding process. Tendering is typically opposed by both generic and brand industries as

³⁵⁴ New Zealand PHARMAC Website, accessed September 5, 2016, <http://www.pharmac.govt.nz/medicines/how-medicines-are-funded/new-funding-applications/>; RBP is also used in some Canadian provinces such as British Columbia for select drug categories.

restricting choice.³⁵⁵ Canadian governments have instead opted for inter-jurisdictional price negotiations for patented drugs, and “tiered” price setting for generics.³⁵⁶ Regardless of the specific reimbursement mechanisms used internationally, most employ some sort of therapeutic referencing and Canadian-style cost-effectiveness analysis.

These methods are prominent in single payer and welfare-state nations in the EU, and notably the UK. The US provides an interesting alternative example. In 1972, the US was one of the first nations to conduct economic ‘technology assessments’ for Congressional decision making when establishing the Office for Technology Assessment.³⁵⁷ However, this and a variety of other early assessment bodies in the US have had only a “limited and indirect” impact on the health care system (Battista and Hodge 1995, 292). These mechanisms were not similar in function and proximity to health decision-making to those that developed in Canada, Australia and Europe. The US differs from many HTA frameworks in that “comparative effectiveness” is the primary focus. Comparative *cost*-effectiveness is more of an implicit factor given the legislative hurdles that US Congress built into Medicare reform:

Comparative Effectiveness Research (CER) is the term used to describe the new \$1.1 billion initiative funded in the US as part of the American Recovery and Reinvestment Act 2009 (i.e. the fiscal stimulus measures enacted in response to the global financial crisis)...Comparative

³⁵⁵ In response to signals by the Council of the Federation regarding tendering, the Canadian Generic Pharmaceutical Association (CGPA) Commissioned a paper in 2012 on the risks associated with that policy. While the Brand industry certainly disagreed with what the risks are, it is also typically opposed to tendering: Paul Grootendorst and Aidan Hollis, “Tendering Generic Drugs: What are the Risks?” study commissioned by the Canadian Generic Pharmaceutical Association (October 2012) accessed June 10, 2013, http://www.canadiangenerics.ca/en/news/docs/10.24.12%20Tendering%20Generic%20Drugs%20-%20What%20Are%20the%20Risks_FINAL.pdf

³⁵⁶ See discussion above. Council of the Federation, “Canada’s Provinces and Territories Realize Real Savings in Healthcare through Collaboration” July 26, 2013 press release, accessed September 5, 2016, <http://www.conseildelafederation.ca/en/latest-news/13-2013/339-canada-s-provinces-and-territories-realize-real-savings-in-healthcare-through-collaboration>

³⁵⁷ This office was defunded and closed in 1995. Princeton University Maintains a Web Archive of its work, accessed November 2, 2016, <https://www.princeton.edu/~ota/>

Effectiveness is the systematic appraisal of the benefits and risks of alternative treatments and other health care interventions (e.g. screening). The inclusion of costs in the appraisal is not explicit. Although some have argued that it is implicit and will lead to cost driven decision making, others point out that Medicare is prohibited by legislation from considering relative costs in the reimbursement decisions.³⁵⁸

In 2010, Congress established a permanent institution, the Patient-Centered Outcomes Research Institute (PCORI), to guide these federal investments (Ali, Hanger, and Carino 2011). PCORI is a public-private governed institute funded by an additional \$1.26 billion Congressional appropriation over 9 years (2010-2019) and also sustained by mandatory fees to health plans and Medicare beneficiaries (Ibid).

The separation of cost from comparative effectiveness research in the US would seem to imply domestic path dependence. Both the market orientation of US institutions and a political aversion to a strong federal role in directing health care decisions have provided considerable ammunition for opponents of federal CER initiatives.³⁵⁹ Canadian and European cost-effectiveness analysis institutions are cited in the US Congressional discourse opposing PCORI, even in its more limited role restricted to non-cost based analysis (CER-only).³⁶⁰ There was considerable Congressional debate on cost-based

³⁵⁸ Centre for Health Economics Research and Evaluation, University of Technology Sydney “Reducing the use of ineffective health care interventions,” Working paper 2010/5 for the New South Wales Treasury, accessed July 10, 2013, http://www.chere.uts.edu.au/pdf/wp2010_5.pdf.

³⁵⁹ For example, Senior Senate Republicans have consistently fought against such a federal role: “[The *Medicare Prescription Drug Price Negotiations Act* of 2007 contains] a provision authorizing consideration of comparative clinical effectiveness studies in developing and reviewing formularies under the Medicare prescription drug program... This is the first step of a dance the Democrats want to do called ‘cutting in on the relationship between doctors and patients.’ Decisions about what drugs patients should take should be made by doctors and patients. I think we should keep the Government out of the exam room.” Senator Mike Enzi (R-WY), Congressional Record, Senate Vol 153, Pt. 7, April 18, 2007: 9107.

³⁶⁰ See statements by: Senate Minority Whip, Senator Jon Kyl (R-AZ), Congressional Record, Senate Vol 157, No 42, March 29, 2011: S1883; Senator Pat Roberts (R-KS), Congressional Record, Senate Vol 155, Pt 24, December 18, 2009: 32689-32690.

HTA. Existing international HTA institutions were framed in strongly negative terms to discourage its adoption in the US:

NICE is notorious for delaying or outright denying access to health care treatments based on comparative effectiveness research that takes into account the cost of the treatment and the Government's appraisal of the worth of the patient's life or comfort...[PCORI] will be the American version of NICE, using CER to save the government money by rationing health care. We tried very hard in the [Health, Education, Labor & Pensions] Committee to insert one word, 'prohibit,' that CER could not be used in any way for cost containment...It was talked about for 2 or 3 days, and then in a very partisan decision, 'prohibit' became a thing of the past.³⁶¹

Ultimately, however, *cost-based* CER was indeed rejected by Congress. The final version of the *Affordable Care Act* 2010 explicitly prevented cost-effectiveness analysis and its incorporation into Medicare decision-making.³⁶² Canadian and UK-style methodologies regarding "dollars per-quality adjusted life year" were expressly prohibited.

Canadian ideas found favorable homes in Europe and the UK but were strongly opposed in the US.³⁶³ While the US did install institutions that were notionally similar, policy reflected domestic preferences and market structure. Like the international adoption of US IP norms, the international diffusion of Canadian ideas and cost-based pharmaceutical review institutions substantially reflected local institutional realities and path dependence.

³⁶¹ Ibid, Roberts 2009.

³⁶² The final *Affordable Care Act* contains a section on Limitations on Certain uses of Comparative Clinical Effectiveness Research: "The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII." Government Publishing Office. 2010. *The Patient Protection and Affordable Care Act, 2010*, Public Law 111-148, page 741, accessed November 2, 2016.

³⁶³ The EU, UK, and US all have large, powerful pharmaceutical industries but EU countries and the UK have much more institutional experience with public health care management. Furthermore, US pharmaceutical companies are known to have a strong institutionalized working relationship with Congress (Sell 2003).

This more organic model of regulatory design provides an alternative to dominate ideas in the IPE literature that stress power. In an elegant and admittedly appealing argument, Drezner (2007) has posited that

great powers [who] oversee large internal markets remain the primary actors writing the rules that regulate the global economy...The key variable affecting global regulatory outcomes is the distribution of interests among the great powers...Smaller state and nonstate actors in the international system do not affect regulatory outcomes, but they do affect the processes through which coordination is attempted (Drezner 5, 2007).

There is certainly some truth to this when considering large structural institutions that may require size and critical mass to sustain. Drezner does provide considerable additional nuance to his argument not reflected in this quote, particularly on the role of domestic governance. However, the approach does not sufficiently account for the real-world intersection and integration of global regulatory standards with local politics and institutions. Smaller actors *can* have a material impact on regulatory outcomes, even if their regulatory approaches and methodologies are not codified or centralized as a formal regime. Institutions and behaviour constraints can also be *informal*. Standard diffusion is not always nor entirely a function of size and the distribution of interests among great powers.³⁶⁴ The diffusion of evidence-based medicine and HTA suggests that market power is insufficient to evaluate regulatory design and international policy diffusion. Historical institutionalism provides a valuable alternative lens.

³⁶⁴ There is also level of analysis issue to be considered. International regulatory standards are only what sovereign nations make of them.

Conclusion

When it comes to implementation of international treaties, states are not unitary actors. Some parts of the bureaucracy are concerned with the technical details of meeting trade commitments in law. Others actively assess the domestic impacts of legislative changes and implement their own related, but separate policies to manage those changes.³⁶⁵ This chapter examined institutional repulsion and resistance somewhat removed from Canada's international trade and intellectual property diplomacy. It argued that to manage growing costs associated with patented technologies, Canada fostered and repurposed evidence-based medicine and health technology assessment institutions. The sequencing of institutional capacity development was critical to success in this effort.

HTA added an institutional layer onto earlier pricing regulation institutions for patented products. Canadian HTA institutions have mitigated the practical market exclusivity provided by the international IP regime by using cost-effectiveness analysis and epistemic expertise to narrow the public procurement market for IP protected products. Canada's public procurement negotiation framework further entrenched the centrality of HTA analysis, and added an additional institutional layer on an already dense institutional complex. Provinces use HTA as a tool to set the parameters and starting point for negotiations with manufacturers of patented medicines. HTA is also used to justify simply 'saying no' to funding requests, or screening out a number of technologies available to the publicly-insured population.

³⁶⁵ Industry Canada officials have acknowledged this in internal briefing communications: "From 1988 to 2002, R&D investment in Canada by pharma MNEs increased most likely because of major IP changes that were made (1987 and 1993) and the negotiated agreement that accompanied these changes, even as the revenue gains for pharmaceutical companies were at least partially mitigated by federal and provincial price controls and increasingly restrictive formularies." John Connell, Associate Assistant Deputy Minister, Industry Canada, "Advice to the Senior Associate Deputy Minister," November 8 2011 - Secret – CCM 227176.

Canadian private markets have recognized the power of these interrelated institutions and their own comparative lack of existing capacity. Despite a notional ability to go the free-market route to controlling patented drug costs, the private insurance sector in Canada has instead opted to pursue the path laid by public institutions. Private insurers increasingly attempted to access and leverage public institutional power.

Institutional layering and conversion also reverberated internationally. Canadian policy innovations in this area diffused through epistemic cooperation and policy learning. Like the diffusion and implementation of trade-related IP protections, the diffusion of compensatory HTA was a country-specific process that ultimately reflected existing *domestic* preferences and institutions. Even the US system adopted similar tools under Obamacare. However, the power of those tools within the actual procurement process was significantly diminished. The experience in Canada, and particularly Canada's HTA policy protégé the UK, was used to raise fears about rationing and dissuade US Congress from adopting cost-based HTA evaluations.

The adoption and international proliferation of evidence-based medicine norms and HTA institutions is significant from a theory perspective. Market power suggest that international regulations should be a function of power and that small states should have little role to play in the design of standards. This work shows that there are productive alternative ways to think about regulatory standard-making where domestic processes are better integrated as part of the outcome metric. Without denying that market power often matters, it is argued that the role of domestic institutions and policy feedbacks are essential and should not be discounted. The innovations of small states can affect regulatory outcomes even if the method of doing so is different from when large states

propagate standards. Furthermore, it is notable that these innovations can serve as a counterweight to other standards favored by powerful actors. This analysis shows that key historical institutionalist ideas of institutional change such as layering and conversion can be significant in an IPE context (Thelen 2003). HI feedbacks within the procurement system should not be ignored.

Chapter 7 – Conclusions and Next Steps

This dissertation addresses the research question: are dominant theories of international political economy such as “market power” sufficient to explain the design and implementation of international intellectual property standards? The dissertation focuses on trade-related intellectual property rights and argues that powerful standard-makers do not unilaterally establish international regulatory standards. Even highly dependent standard-takers can significantly shape international regulatory outcomes and protect domestic institutional sovereignty. Market power is an important factor but is not sufficient to explain trade-related regulatory agreements and associated institutions. Other theoretical frameworks such as historical institutionalism (HI) help to create a more accurate and nuanced picture of state preferences and policy processes. The current literature on trade and international regulatory regimes is incomplete and must consider factors beyond negotiations. International regimes establish consistent standards to facilitate cooperation and predictability. However, their primary function is often to shape domestic laws and regulations. International agreements arise out of, and are inseparable from, domestic economic regulation. Existing regulatory standards lay a path for future standards. Domestic institutions and the politics of implementation are thus integral to international regulatory outcomes.

Historical Institutionalism in IPE

The application of historical institutionalism to international political economy (IPE) is a relatively new and contested approach (Farrell and Newman 2010; Drezner 2010). When

implementing trade-related regulatory regimes, international standards clash with entrenched domestic standards creating policy feedbacks. Feedback is a core concept from historical institutionalism that views past policy decisions as constraining future outcomes through path-dependence: “when policy creates politics” (Pierson 2004). Established institutions and entrenched actors adapt to changing circumstances through institutional layering. Existing institutions are also converted to address new policy challenges.

The dissertation argues that these policy feedbacks can repel and resist new international standards and reinforce domestic power to a surprising extent. It examines the negotiation and implementation of trade-related intellectual property standards and identifies different varieties of policy feedback. These include regulatory, judicial, procurement, and international relations feedbacks. It shows that institutional feedback and sequencing dynamics can significantly shape policy outcomes.

Canada as a Critical Case

This dissertation employs the Canada-US relationship as a critical case for the market power hypothesis. Canada is a critical case due to overwhelming trade dependence on the US and the critical link between IP and trade. Given Canada’s overwhelming trade dependence, we would expect market power to be the most important driver of outcomes in the Canada-US trade relationship. However, Canadian institutions shaped the negotiation of trade and regulatory agreements and the final domestic regime produced when implementing those agreements. This process had a legacy effect for future international agreements. Canadian policy feedbacks preserved and reinforced a strong

role for existing institutions as the trade context evolved and as regulatory standards progressed over multiple agreements.

A foundational “policy that created politics” was Canada’s pre-TRIPS compulsory licensing regime. This 1920s-era regime modeled after British law was significantly expanded in 1969 to drive down pharmaceutical prices through the granting of compulsory import licenses. The policy facilitated the growth and consolidation of a powerful Canadian generic pharmaceutical industry. These domestic interests found alignment with sub-national provincial government purchasers of patented technologies. The interest coalition has since significantly shaped intellectual property (IP) policy including Canada’s negotiation and implementation of international treaties.

Canada implemented US-style IP rights to promote domestic research and development (R&D) as a critical concession for broader trade liberalization with the US. However, at the domestic institutional level Canada has consistently resisted and mitigated the full extent of those protections. Feedbacks within the regulatory, judicial, and procurement systems introduced important constraints to global IP standards. These implementation constraints (see Figure 6.1 for an overview) and layering and conversion strategies (see Figure 6.7) demonstrate how historical institutionalism can be a more effective framework for analysis than market power in some cases.

Chapter 3 discussed the establishment and evolution of Canada’s powerful regulatory price control institution, the Patented Medicines Prices Review Board (PMPRB). A market power approach would not predict Canada’s ability to powerfully shape this institution to constrain the impact of patent protection. Yet time and again, the

PMPRB has been leveraged and shaped in response to evolving trade-related IP standards.

A key feature of the regulatory institution was its flexibility and open-ended powers. This has allowed it to evolve and adapt as the trade-related IP context changes over time. PMPRB powers were protected by Canadian officials in the multilateral trade negotiation and the institution was strengthened in the context of NAFTA implementation. In 2017, the PMPRB is again being strengthened to further protect consumers from patented pharmaceutical prices and in the context of new IP protections under the Canada-EU Comprehensive Economic and Trade Agreement (CETA).

Chapter 4 showed how other regulatory feedbacks critically shaped Canada's implementation of US-style patent linkage provisions. Market power theory would predict that standard-taker nations simply adopt the more powerful standard-maker's regulatory approach. Partial diffusion or the implementation of significant policy mitigations would suggest that a market power explanation is not complete. Patent linkage is a key innovator protection, however Canada implemented this narrowly in comparison to US standards and in comparison to other policies that constrain IP protections, such as price controls (see Figure 4.1).

Implementation of this policy produced a Canada-specific litigation mechanism and a significantly diminished regime in comparison to US *Hatch-Waxman Act* standards. The path forged by the US system of patent linkage was only partially exported to Canada. It clashed with a domestic path, legal institutions and an institutionalized interest coalition. Regulatory feedbacks continue to shape the patent linkage regime. Protections

were diminished following stakeholder lobbying in the late 1990s. Furthermore, in 2017 the regime will be fully overhauled in the contemporary CETA implementation context.

Chapter 5 examined feedbacks in the judicial system that have significantly narrowed the very definition of patentable utility in Canada and thus constrained the full impact of international treaty language. As a state-level approach, market power is not well suited for considering dynamics within the black box of the state. As such, it does not hold much insight on the affairs of domestic judicial institutions, despite their clear importance on patentability outcomes and the interpretation of domestic law.

Feedbacks in the judicial systems have created cross-national divergence on patentability outcomes and have significantly impacted Canada's international relations with the US. The judicial branch has constrained the practical extent of market exclusivity provided by the international intellectual property regime. Canadian legal institutions are shown to be resilient in the face of international regulatory standards and bilateral pressure to address Canada-specific patent invalidations under the promise doctrine. Market power and "naming and shaming" by powerful US state actors have negligible importance at the legal institutional level.

Finally, Chapter 6 examined policy feedbacks related to Canada's procurement regime for health products. Canadian policy actors have adopted strategies to limit government market exposure to expanded IP protections. Market power predicts that small standard-takers would not be *effective* in significantly mitigating trade commitments that are contrary to the interests of larger market powers. Contrary to this perspective, Canadian institutions were converted to provide a rigorous review process

that would help governments determine what patented technologies would be available in Canada, and at what price.

The success of these public institutions has attracted the attention of Canadian private insurers who have attempted to harness this public institutional capacity. The ideas and methodologies that Canada developed were very also successful and spread internationally through epistemic community cooperation. Canada was particularly important in informing the development and approach of UK institutions. Similar institutions now help to mitigate the impacts of IP protections and patented pharmaceuticals in many international jurisdictions. In other words, domestic policy feedbacks have reach and impact beyond domestic politics. Canada's repellence feedbacks reverberated internationally. Contrary to market power predictions, small states can significantly impact regulatory outcomes. However, in keeping with an HI perspective, policy tools diffused in various path dependent ways reflecting existing domestic institutions. This mechanism of policy diffusion offers an alternative to diffusion based on imposition of standards under market power or naming and shaming. .

Contribution

This dissertation makes both theoretical and empirical contributions. It offers a new way of thinking about international trade and regulatory regimes by temporally extending the dependent variable. Agreement is only the starting point for a much longer policy process that includes implementation and related policy feedbacks. Trade agreements are historically cumulative and new agreements tend to grow from domestic regulations and

past agreements.³⁶⁶ As such, the dependent variable should be the regulatory regime “in domestic practice” rather than “as negotiated.”

From a theory perspective, this dissertation addresses a central criticism of historical institutionalism. Critics argue that HI is most aligned with “reinforcing” policy feedbacks and that the existence of “resistance” and “repellence” would tend to undermine the approach. The dissertation shows that “reinforcement” is not the only dynamic that supports HI when resistance and repellence are rooted in path dependent domestic policy choices and institutions. In a sense, they are a dynamic of the *broader* reinforcing domestic feedback process.³⁶⁷ In such cases, resistance and repellence do not undermine the framework, but rather significantly support it.

While it is tempting for the purposes of theoretical parsimony to privilege market power, this can obfuscate important nuance and determinants of policy outcomes. States are not unitary actors. Policy is complicated. It is increasingly difficult to separate out international politics from domestic regulation. The conventional notion is that international regimes are about constraining state actor activity in the international sphere. However, this dissertation illustrates how regulatory regimes are also about influencing domestic behaviour and regulation. International trade is fundamentally about domestic economic policy.

This dissertation shows that we must look beyond market power to fully understand international IP standards. Historical institutionalism helps to inform a more representative picture of how international regulatory standards are designed and take

³⁶⁶ A practical illustration of this is that trade negotiations are structured around issue chapters that build off of the same framework as issue chapters from past agreements. They tend to update those previously agreed standards.

³⁶⁷ Trade liberalization and globalization is not some permanent end state-of-being. The legacy of domestic institutions and politics continue to feedback in response to globalism.

shape. The dissertation does not suggest that one framework or theory is *most* appropriate. Power factors and institutional factors tend to combine to produce outcomes. Ultimately, a pluralist lens is needed to reflect causal combinations as well as the possibility of equifinality.

In mediating between market power and HI, the dissertation helps to show how multiple theoretical perspectives can be combined to explain outcomes. Market power is a good starting point to contextualize regime incentives but institutional power cannot be abstracted away from the analysis. As indicated, the dissertation addresses a core criticism of HI identified in the literature. It shows that ‘repellence’ can be consistent with path dependence.

From an empirical perspective, it contributes a detailed account of IP-specific trade and regulatory policy through substantial archival research and unique elite interviews. It shows a side to policy making that is not already captured in the negotiations literature. The dissertation puts the technical disciplines of price regulation, intellectual property law, and health economics in their proper *political* context. These empirical areas will be completely new to many IPE scholars. The combination of perspectives and diverse spheres of knowledge amalgamated within an IPE framework is original and helps to fill acknowledged gaps in the literature on IP and trade agreement implementation (Sell 2010). Scholars in the technical disciplines of IP law and health economics will also be interested in its empirical contributions and the historical chronology that ties this political analysis together.

For example, the study of trade negotiations is often agent-centric (actor and personality-driven) and can gloss over the very important details of integration into

domestic law and politics. Similarly, while Canada's patent linkage regime and the "promise doctrine" are well known by IP law practitioners, its sources and trade-related context is not robustly addressed in that literature. It is identified and branded as "judge-made law," but is not really explained. The promise doctrine is as much an international relations issue as it is a domestic legal issue.

Similarly, the technical and highly positivist discipline of health economics typically aims to *remove* politics from decision-making. Politics do not typically factor into the narratives of the discipline. However, politics are absolutely central to its very purpose and current function. Arguably, Health Technology Assessment (HTA) only enjoys its current prominence in the policy discourse due its functional role in curbing drug costs *created* by trade-related IP reforms. Yet politics, trade, and IP are rarely given consideration by the HTA community.

Finally, this dissertation has implications for the study of regimes in other issue areas. The sources, implementation, and impacts of regimes should be assessed together. Negotiation outcomes and "win sets" need to be reassessed following implementation and with the benefit of real-world experience under the regime. Those who wish to design successful international regimes should consider implications and potential barriers due to domestic politics and entrenched institutionalized interests. Future regimes could include specific provisions and protocol for domestic implementation to ensure final regulatory outcomes reflect what was negotiated. Nullification or impairment provisions³⁶⁸ have not been used for intellectual property matters. However, due to the power of domestic path dependence we might reasonably want to consider their use in

³⁶⁸ For example, provisions that provide remedies for damage to a country's benefits and expectations from membership in an international regime due to another country's change of policy or failure to carry out agreed upon obligations under the regime. This language mirrors the WTO conception.

other regime issue areas. This could help prevent indirect shirking on commitments, and ultimately, promote successful cooperation.

Limitations

As acknowledged by past work, historical institutionalism is not well suited to ‘predictive’ insights, particularly over the longer run (Farrell and Newman 2010, 619). HI is often backward-looking and therefore other factors are needed to fully explain change. Those who point out that the predicted effects of path dependence are *too powerful* clearly have a point (Drezner 2010, 795). Public policy is not a QWERTY keyboard.³⁶⁹ The QWERTY keyboard has value as a conceptual heuristic, but should not be mistaken as the basis for a positive law. Technological progress cannot be explained solely by looking at the legacy of past technologies. Similarly, policy innovation cannot be explained solely by looking at past policies.

This research supports the central HI prediction that feedbacks will tend to reflect embedded actor interests where they have proximity to regulatory decision making processes (Farrell and Newman 2010, 620).³⁷⁰ However, this dissertation suggests that proximity is not the full story and feedbacks also tend to have functional and normative elements. For example, we might predict that policy actors will be more successful when helping to achieve practical state problems such as economic development or budgetary

³⁶⁹ The example of the QWERTY keyboard is raised as a key illustration of path dependence. QWERTY is the universal English language computer keyboard today, but is not as ergonomic or optimal as potential alternatives. QWERTY was used for early typewriters for mechanical reasons, and it has endured as the standard due to path-dependence. New generations of technology incorporated the previous standard, which had a reinforcing effect.

³⁷⁰ Specifically, Farrell and Newman (2010) note: “We may predict that where policy feedback loops have occurred, variation in states’ preferences over existing institutional bargains will depend on which interest groups have succeeded in becoming embedded in the relevant regulatory decision making structures. Those interest groups that have succeeded in embedding themselves within the relevant institutional frameworks will unsurprisingly use their advantageous position to pursue regulatory policies that favor them.” (620).

cost control. This was the case for both the generic pharmaceutical industry and the HTA epistemic community.

Perhaps we are examining the wrong predictive question by asking, “where and when will feedbacks happen?” Historical feedback is present in *every* facet of human and social life. History is the venue where actors negotiate the future. History is the foundation that determines the distribution of actor resources. Self-reinforcing feedback is a continuous phenomenon. Perhaps a more relevant predictive question for future evaluation is “when will policy feedbacks really matter as an independent source of power?” It is clear that feedbacks will matter when they are associated with a powerful nation with the capacity to project power globally (Sell 2010). This dissertation suggests that feedbacks are also likely to be important where there is an exogenous global challenge to domestic sovereignty, a given social bargain, or a fundamental distribution of resources. Furthermore, ideas and institutions that are useful in insulating domestic actors from exposure to the international market are likely to diffuse organically for functional reasons. This contrasts with extant narratives of policy diffusion that focus on a powerful actor leveraging market power to impose its will. This is only a subset of the mechanisms of regulatory policy diffusion.

Another potential limitation is what some HI-purists might view as an inherent conflict between HI and process tracing,³⁷¹ despite their frequent pairing. HI aims to study longer-run causes and long-run outcomes from an historical perspective. It focuses on macro-historical trends and aims to avoid getting bogged down in agent-based accounts or policy micromechanisms. Process tracing methodology, on the other hand, is often used to evaluate causal mechanisms associated with shorter-run policy and

³⁷¹ See Pierson (2004).

decision-making processes. As such, a temporal compromise to balance theory and method seems appropriate. This dissertation avoids overemphasis of micromechanisms within an individual trade negotiation. It has attempted to achieve balance by looking at policy processes over a longer time horizon for both the independent and dependent variables. However, it has stopped well short of macro-historical analysis so as to maintain relevance to contemporary policy processes.

A third potential limitation is empirical. While capturing many interesting interview insights, the topics under study are now somewhat dated and this impacted the ability to do many interviews. For example, some of those most associated with Canada's early Evidence Based Medicine and Health Technology Assessment institutions such as David Sackett and Jill M. Sanders have passed on. Also, much of the subject matter herein is legal in nature. Government lawyers were expressly reluctant to comment on confidential subject matter. When embarking on this research it was thought, erroneously, that this time gap would actually help to mute the political nature of the subject matter. However, even after several decades some officials contacted for interviews still did not feel comfortable commenting on this highly political subject matter, or would not do so with attribution. It is surprising how political these topics remain, decades later.³⁷² The now obvious reason for the political sensitivity is that these same issues and institutions (PMPRB; the patent linkage regime and dual litigation; patent term restoration) are among the most central political topics in the *current* trade and regulatory context. The dissertation illustrates that these issues never *really* went away.

³⁷² A relatively low 29% interview request success rate actually supports the central thesis by helping to illustrate that these political sensitivities persist over multiple agreements.

Nevertheless, this study was primarily based on archival research, information obtained under the *Access to Information Act*, unpublished statements by officials and material from a wide range of sources in the public domain. Supplemental interviews were also highly instructive and the research was successfully advanced by many critical insights shared on an anonymous basis. Unlike negotiations, the written historical record on many of these issues, including implementation, case law, and institutional history, is actually quite good. Policy analysis in this area proved to be more a matter of “learning where to look.”

One additional question that might arise in readers’ minds is the actual *extent* of the constraints provided by each of the various institutional layers discussed.³⁷³ After all, the popular media is full of narratives regarding expensive drugs. Canada’s drug spending (including non-patented generic drugs and mark-ups by wholesalers and pharmacies) are indeed among the highest internationally in per-capita terms. If Canadian price regulators are indeed powerful, why were Health Technology Assessment and purchasing institutions even necessary?

It should be remembered that the PMPRB was always designed to hold prices to the median of rich industrial countries, and was explicitly intended to lock in Canadian patented drug prices at around 80% of US prices.³⁷⁴ As of 2015, Canadian patent drug prices were nowhere near this benchmark. According to the PMPRB, the average price ratio at market exchange rates for Canada was 1.00 to 2.70 in the United States,³⁷⁵ or

³⁷³ See Figure 6.1 for an illustration of “magnitude” at various institutional levels.

³⁷⁴ Harvie Andre, Second Reading of Bill C-22, House of Commons Debates, November 20, 1986, 1372, accessed October 15, 2016, http://parl.canadiana.ca/view/oop.debates_HOC3302_01/1374?r=0&s=1

³⁷⁵ PMPRB Annual Report 2015. Canada still has among the highest drug expenditures per capita internationally, but US patented drug prices are well above Canada and the rest of the world. For this reason, it is significant that the PMPRB uses a median price test rather than an average. Another point to note is that the PMPRB does not have access to confidential rebates noted in Chapter 6, nor data on rebates

36% of US prices. The PMPRB also plays an important price stability role to prevent large price increases that would otherwise be possible under unrestricted patent protection.³⁷⁶ Fundamentally, the institution is incredibly powerful but has not been used *aggressively* to drive prices down over time. This essential insight has been clearly articulated by Health Minister Jane Philpott when signalling to Canadians that she intends to adopt a more activist approach:

I'm working quite determinedly with organizations within Canada that set the prices of prescription medications. It's a little known fact that actually we have a lot of control over that. That with a few regulatory changes and guidance changes for this organization that does the price review on pharmaceuticals we can actually dramatically lower the cost of prescription drugs.³⁷⁷

In other words, Canada has the power it needs to further constrain drug costs under existing legislation (as implemented under its trade deals).

In contrast to politically popular positioning on “out of control” drug costs, Canada has actually significantly constrained the impact of *patented* pharmaceuticals. According to the PMPRB, patented drug sales at the factory gate were \$15.2 billion in 2015. This is only 52% of the total \$29.2 billion in prescription drug spending reported by the Canadian Institute for Health Information (CIHI).³⁷⁸ The top-line prescription drugs spending figure is used in international spending-per-capita comparisons and thus informs much of the basis for the expensive drugs narrative in Canada. The other half of spending is on non-patented generic prescription drugs, which are known to be among the

in most other countries. International price comparisons are fraught with challenges. PMPRB comparative analyses based on list prices are sufficient as general indicators but should be treated with caution. In particular, policy makers should get a better sense of actual health system cost-drivers before devising future policy.

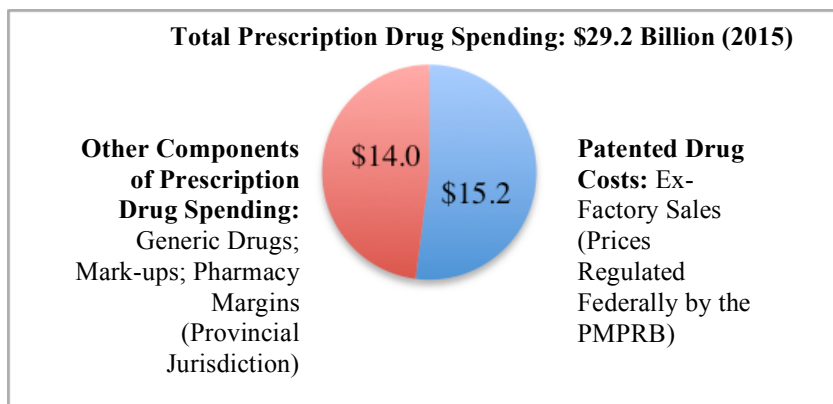
³⁷⁶ In 2014, Canadian prices were closer to 41% of US prices. US prices are not controlled as they are in Canada.

³⁷⁷ Jane Philpott, CBC program *The Fifth Estate* “Canada’s Drug Problem” January 13, 2017.

³⁷⁸ CIHI data as cited above; PMPRB Annual Report 2015.

highest priced in the world,³⁷⁹ and middlemen mark-ups at the wholesaler and pharmacy industry level. Pharmacist compensation (distribution profit) is hidden in the prescription drug cost line item. This is depicted in Figure 7.1. Canada’s “drug problem” is really a market design and market fragmentation problem.³⁸⁰

Figure 7.1: Patented Drugs Comprise 52% of Total Prescription Drug Spending (Billions)³⁸¹



Additionally, Canada is not a single payer market. Institutionalized market fragmentation between public and private, and between provinces entails that Canada’s pharmaceutical market is much more similar to the US pharmaceutical market than to single payers in Europe. Some of the excess in Canada’s overall drug spending is due to a lack of HTA and negotiation institutions on the private side of the market. This strongly supports the institutional thesis advanced herein rather than undermining it in any way. Similarly, the fact that other jurisdictions have used Canadian ideas and other institutions

³⁷⁹ PMPRB, Genics360, Generic Drugs in Canada, 2014, February 2016, accessed April 2, 2017, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1233&lang=en#exec>

³⁸⁰ Even those most critical of high per-capita drug spending in Canada acknowledge the central issues of a multi-payer “patch-work” system and comparatively higher generic drug prices. Morgan et al. (2017) note that the price of high volume generic drugs are 47% lower in the US, 60% lower in Sweden and 84% lower in New Zealand (Morgan, Li, Yau, and Persaud 2017).

³⁸¹ CIHI, National Health Expenditure Trends, 1975 to 2015, data tables, accessed September 22, 2016, https://www.cihi.ca/sites/default/files/document/nhex_2015_datatables_en.zip; PMPRB Annual Report 2015.

more aggressively to constrain their total expenditures does not undermine the significance of Canadian efforts. And as Canada moves in the context of new IP protections under CETA to further constrain drug costs through PMPRB reform in 2017, the significance and inherent power of Canadian institutions has become all that more apparent. Time and again, Canada's domestic institutions significantly narrow the practical extent of market exclusivity provided by the international IP regime. Powers to regulate were protected through exemptions to nullification or impairment that Canada was careful secure (see chapter 3). Canadian courts have consistently upheld the constitutionality of the federal government's right to regulate patented drug prices. New institutional layers have been employed to further enhance Canada's capacity in this regard.

Future Research

There are two principle avenues where this study can help to inform future research: Opportunities to apply the framework to other regime issue areas; and, opportunities to extend the research over space and time. This dissertation has presented a "varieties of policy feedback" framework may be useful as a guide for analysis of trade agreements and regimes in other issue areas. For example, when evaluating an international agreement, analysts could ask a series of questions: How is the force and effect of the new rules impacted by their implementation?; How does implementation alter the conception of "winning" the negotiation?; Is this influenced by regulation, case law, procurement, or international relations feedbacks?; How do domestic interests and actors react?; What strategies do they adopt to manage change? Answering these questions will

help IPE and regime theory better account for the real-world institutional drivers of policy.

IPE and regime scholarship has been driven by the foundational problem in international relations: “how order emerges from anarchy.” However, contemporary global regulatory problems suggest a shift in focus may be needed. The more contemporary root problem of importance is “how can nations successfully address pressing global problems?” The dissertation assesses how global regulatory initiatives interact with local institutions. This is a first step to understanding barriers to success and how to design better regulatory systems that can accommodate existing domestic institutional realities. To be successful, we must consider the practical intersection of global standards and domestic institutions.

Secondly, this research could be extended over space and time. Recent events in the United States have called into question the future of US-led rules-based international trade. The Trump world outlook embodies the “market power” perspective in international political economy: It’s the size of your market that matters. In this context, this dissertation offers an alternative perspective and hope to even the most trade-dependent of nations. It argues that when considering trade and regulatory agreements, market size is only one part of the equation. Institutions matter and can help to mitigate significant market power asymmetry. Re-negotiation and re-implementation of NAFTA should be viewed under the lens of this alternative perspective. It would also be useful to test these insights over a macro-historical context to capture even longer-term causes and longer-term outcomes than explored herein.

This perspective could also be tested for different treaty types and different national institutional contexts. For example, one could test how dynamics differ between “dualist” systems like Canada and “monist” systems such as the Netherlands, France, and Spain.³⁸² One might assume that there are few implementation dynamics in some monist systems; however, there are undoubtedly other related national dynamics to consider when introducing new complex regulatory measures that reach into domestic life. Furthermore, as noted, the history of the General Agreement on Tariffs and Trade (GATT) suggests that monist systems struggle to uphold direct application for complex agreements (Jackson 1992, 333-4). Political implementation dynamics would be particularly interesting (and challenging) to study in the EU where parts of so-called “mixed agreements” can be provisionally applied under EU jurisdiction, and other parts require national ratification (and can be held up by sub-national actors who aim to exact subsequent concessions).

From a theoretical perspective, there is no doubt that future work could also offer greater specificity on exactly *how* various perspectives such as market power, historical institutionalism, and constructivist norms and identities can be combined productively within a pluralist framework. The question is how can scholars transcend the nomothetic problem of false precision on one perspective (market power) while avoiding the ideographic problem of *imprecision* due to the empirical reality of equifinality? In other words, when abstracting for theory, how can we find room between the perspective that “only one factor *really* matters” and the opposite challenge of an absence of theory where “everything matters”? The use of necessary and sufficiency relationships is a promising

³⁸² See discussion Chapter 4. In monist systems, treaties can be notionally “directly applied” or “self-executing” and invoked in law. Implementation provisions are sometimes also used (Jackson 1992; Halpérin 2014, 174).

way forward. For example, this dissertation demonstrates that market power is a necessary but not a sufficient condition for setting an international standard. Similarly, it found that financial strain is a necessary but not a sufficient condition for the international diffusion of mitigating cost-control institutions. These types of analyses and insights could be useful to inform the design of future regulatory approaches.

From an empirical perspective, this work suggests that the analysis of trade and regulatory regimes could be more integrated with respect to time. It is important to capture trade-offs and policy linkage between issue areas within the same trade agreement as is typical in the negotiations literature. However, it is equally important to examine specific issue-areas (e.g. intellectual property and investment) to assess how institutional history and past policy choices impact the evolution of policy outcomes over time and over multiple agreements. For example, each issue-area in a trade agreement (e.g. each negotiation chapter) has its own stakeholders, norms, politics, regulatory traditions, and historical practices. These factors can be as relevant as specific negotiation trade-offs made within a single trade deal. Market power is naturally more suited to analyzing power distribution dynamics and trade-offs made within a single negotiation. Historical institutionalism is more suited to in depth examination of policy and politics in a specific regulatory domain and explaining the drivers of state preferences within an issue-area over time. The present analysis of intellectual property issues over multiple agreements shows that institutions and institutional feedbacks can be just as significant as market power, and at times, even more so.

ANNEX

ANNEX A to Chapter 3

PMPRB Pricing Categories and Associated Tests, effective January 1, 2010³⁸³

Category	Definition	Allowable pricing
Breakthrough	A breakthrough drug product is the first one to be sold in Canada that treats effectively a particular illness or addresses effectively a particular indication.	Median International Price Comparison (MIPC) test: median of the ex-factory prices (the price manufacturers sell to wholesalers and other customers) of the same strength and dosage form of the same patented drug product for each country listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States)
Substantial Improvement	A drug product offering substantial improvement is one that, relative to other drug products sold in Canada, provides substantial improvement in therapeutic effects.	The higher of: <ol style="list-style-type: none"> 1. Therapeutic Class Comparison (TCC)- the highest existing price in the same class; and, 2. Median International Price Comparison (MIPC) test: the median international price for that same product
Moderate Improvement	A drug product offering moderate improvement is one that, relative to other drug products sold in Canada, provides moderate improvement in therapeutic effects.	The higher of: <ol style="list-style-type: none"> 1. Midpoint of: <ol style="list-style-type: none"> i. Top of the TCC test comprised of all drug products identified by HDAP pursuant to section C.8.7* and ii. MIPC test; and 2. Top of the TCC test comprised of all drug products identified by HDAP pursuant to section C.8.7.* If it is impossible to conduct a TCC test (i.e., unable to derive comparable dosage regimens or the prices of the drug products used for comparison purposes appear to be excessive), then use the MIPC test.
Slight or No Improvement	A drug product offering slight or no improvement is one that, relative to other drug products sold in Canada, provides slight or no improvement in therapeutic effects.	<ol style="list-style-type: none"> 1. Top of the TCC test comprised of all comparable drug products identified by HDAP pursuant to section C.8.9** 2. In the exceptional cases where HDAP does not identify any comparable drug products, use the lower of <ol style="list-style-type: none"> i. the bottom of the TCC test comprised of all superior drug products identified by HDAP pursuant to section C.8.10*** and

³⁸³ PMPRB, "Compendium of Policies, Guidelines and Procedures," accessed December 20, 2015, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492#c61>

		<p>ii. the MIPC test.</p> <p>3. If it is impossible to conduct a TCC test (i.e., unable to derive comparable dosage regimens or the prices of the drug products used for comparison purposes appear to be excessive), then use the MIPC test.</p>
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*C.8.7 For new patented drug products that represent a moderate therapeutic improvement, HDAP will identify drug products with the same approved indication or use over which the new patented drug product represents a moderate therapeutic improvement.

**C.8.9 For new patented drug products that represent slight or no therapeutic improvement, HDAP will first attempt to identify comparable drug products, based on the primary and secondary factors set out in section C.6.1, with the same approved indication or use as the new patented drug product under review.

C.6.1 The following factors are to be used in recommending the level of therapeutic improvement of a drug product:

Primary Factors

- Increased efficacy
- Reduction in incidence or grade of important adverse reactions

Secondary Factors

- Route of administration
- Patient convenience
- Compliance improvements leading to improved therapeutic efficacy
- Caregiver convenience
- Time required to achieve the optimal therapeutic effect
- Duration of usual treatment course
- Success rate
- Percentage of affected population treated effectively
- Disability avoidance/savings

***C.8.10 If no comparable drug products are found, HDAP will identify all drug products that are considered superior in treating the approved indication or use, based on primary and secondary factors.

ANNEX B to Chapter 3
Excerpts from Minister Michael Wilson Speeches 1991-1993

Speaking Engagement	Quote	Significance
Financial Post Conference on North American Free Trade Montreal QC, April 25, 1991	“The Canadian requirement for secure market access and the need to guard against protectionism led us to negotiate the [FTA] with the United States...And it has driven our decision to join...trilateral free trade talks”	Illustration of the obvious point that US market access was a clear Canadian priority.
Investment Dealers Association, Whistler BC, June 17, 1991	“[Foreign Direct Investment] as you know very well, brings benefits to Canada and its Economy in the form of: technology transfers; international management expertise; production know-how and product innovation; creating and preserving high value-added jobs and export opportunities	Shows key objectives of Canada’s investment strategy for the knowledge-economy
Softworld Trading Forum and Conference, Vancouver BC, September 23, 1991	“You face all of the problems encountered by technology-based companies. Competition is growing. You need to finance R&D on a continuing basis. You have a limited window of opportunity within which to reach the market”	Illustrates the challenges faced by knowledge-economy companies including high input costs and limited time to recover investments (in this case for software)
University of Western Ontario Conference at Sutton Place Hotel, London ON, October 3, 1991	“The FTA has already shown its true colours by mitigating the domestic impact of a global recession and of world-wide adjustment trends...The [FTA] dispute mechanism is proving to be an effective shield for the enhanced market access the agreement provides.”	Shows the centrality of rule-based trade—specifically a dispute resolution mechanism—to protecting Canadian interests when dealing with a major market power.
Canadian Luncheon at the Davos Annual Meeting February 1, 1992	“The size of the U.S. market, its proximity, and familiarity, the continuing position of the U.S. as a world technology leader – as well as the opportunities provided by Canadian companies as a result of the Canada-U.S. [FTA]—will mean that the U.S. will continue to be an important export growth market. We want to capitalize on FTA-related opportunities and increase the importance of advanced technology exports and related investments.” “If [Bill C-91 IP changes] sound like an invitation for pharmaceutical firms...to increase their investment in Canada, that’s just what it is”	Illustrates the importance Canada placed on access to the U.S. market and developing its domestic pharmaceutical industry.
Arthur Andersen Symposium St. Charles II, June 2, 1992	“The GATT was the foundation upon which the Canada-U.S. Free Trade Agreement (the FTA) was built. Equally it is the basis for negotiation other trading arrangements, such as the proposed [NAFTA]. Furthermore, the GATT will provide the basis for expanding continental trade with the emerging European Community and the high-growth Asia-Pacific region.”	Shows how policy makers view trade agreements as cumulative. New standards build on previous standards.
Notes for an	“Canada has benefited from the dispute settlement process	Shows how rules-

Speaking Engagement	Quote	Significance
address at the conclusion of the North American Free Trade Agreement August 12, 1992	<p>established in the FTA. We have won a majority of cases. And now we have negotiated a strengthened dispute settlement system with safeguards to ensure that the system runs fairly. The rule of law, not power, will prevail in settling disputes.”</p> <p>“The NAFTA itself need not be a closed club. Perhaps, too, this deal will lend some impetus to the worldwide trade negotiations in the GATT, where Canada has been playing a leading role”</p>	<p>based trading and dispute resolution institutions are explicitly intended to mitigate power factors.</p> <p>NAFTA was seen as an impetus for expansion and future trade diplomacy.</p>
Wall Street Journal Conference, New York, September 24, 1992	“Rather than hindering the multilateral process, the NAFTA should provide an impetus to the successful conclusion of the Uruguay Round... It will ... show other newly industrialized and developing countries that they, like Mexico, can successfully enter into freer trading relationships with developed countries. This is very important to us.”	Illustrates the view of NAFTA as a pump-primer.
Binational Conference on Trade Disputes: Settlement Mechanisms and Future Prospects October 20, 1992	“The absence of effective dispute settlement procedures [in NAFTA] would create a situation in which raw economic power, rather than established rules and procedures, dictate the outcome of trade disputes.”	Reiterates the centrality of rule-based trade, specifically, a dispute resolution mechanism, to protecting Canadian interests in dealing with a major market power.
Pharmaceutical Manufacturers Association of Canada, Ottawa ON, October 30, 1992	<p>“The introduction of Bill C-91 improves the business environment for your sector as well as demonstrates the government’s strong commitment to your industry. Bill C-91 brings Canadian intellectual property practices more in line with those of other industrialized countries...The Government of Canada remains committed to early passage of the bill.”</p> <p>“We are also please that a number of these [\$500 million new R&D] investments [are] outside Que & Ont. I hope that as circumstances warrant, you can broaden this regional spread.” (Hand Written)</p>	Shows a key objective of government was for R&D to be distributed across the country. The PMPRB is tasked with tracking this.
Conference “Les Grands Enjeux” Montreal, QC November 25, 1992	<p>“Two other key factors [in addition to prosperity and competitiveness] are investment and research and development... the government introduced Bill C-91 into Parliament for the purpose of bringing our patent protection more into line with other countries...”</p> <p>Over the last ten months [major innovative firms] have announced over \$500 million in new R&D investment, in Canada, contingent upon successful passage of C-91”</p>	<p>A 4-page “Insert on C-91” was added to the speech to address the high politics of C-91.</p> <p>Typifies how Wilson leveraged promised investments by the pharmaceutical industry to make the case for Bill C-91.</p>
An Evening with Rene Soetens, Pickering ON,	“A university of Toronto Study...[has] suggested that Canada have faced an even deeper recession without our participation in the Free Trade Agreement”	Shows how the argument for NAFTA was build on the

Speaking Engagement	Quote	Significance
November 25 1992	<p>“NAFTA covers many services that weren’t covered in the FTA...”</p> <p>“The FTA, and now the NAFTA, create tremendous opportunities for Canadian companies...we can build on the considerable opportunities that having access to a market of nearly \$8 trillion in national income and over 360 million potential customers”</p>	successes of the FTA. It aimed to preserve US market access.
Talking points Faxed to Minister November 25, 1992 in response to Canadian Press wire by Dennis Bueckert on opposition to Bill C-91.	<p>Talking Point: “[C-91] is good for Canada: more investment (\$500 M plus); more high skilled jobs; more research; better medicines; strong price control; reward for innovation... Canada has been holding its own, <u>but</u>, if we want investment we must act now, [Canada is] at a critical juncture...Note [the] track record of C-22:[drug] prices [increasing] below [the consumer price index]; investment up; jobs up.”</p> <p>Minister Wilson additional hand written notes: “[Canadians] say they want R&D, [Investment], high tech jobs...But you can’t just wish this...C-91 will help... Delaying treaties risks [investment]; Should concentrate on price control regime”</p>	Shows responsible Minister’s thinking and that price control regime was central to legitimizing increased patent protection; illustrates how the legacy of previous institutions under C-22 1987 was key to the argument for C-91 1993.
Talking points Faxed to Minister November 25, 1992 (same as above)	<p>“<u>CP Wire:</u> New Legislation Threatens thousands of job in [Canadian] owned industry. <u>Rebuttal:</u> Generics said the same thing in 1987—yet they have continued to grow -- & they can grow under the new regime – at rates at or above the average growth rate in the pharma industry. <u>Note</u> brand name have created more jobs since 87 than total employment in generic sector.”</p> <p>“<u>CP Wire:</u> The legislation will drive drug cost up by \$1 [billion] per year. ‘seniors will be hard hit by the legislation. <u>Rebuttal:</u> This is an outrageous lie. The cost will be [\$]129 [million] cumulative [between] 1992 – 1996. – This is \$1/per [Canadian] per year – as compared to \$500 m of investment benefit & the economic effort that will have.”</p> <p>Michael Wilson notes: “Who benefits from cures [?] – seniors. Who pays [?] – gov’t / taxpayer”</p>	Shows the economic impact assessment that was critical to making the case. Shows government actively rebutting generic industry messages.
Building a More Prosperous Canada” Speech December 2, 1992 House of Commons	<p>“In entering the NAFTA negotiations, Canada’s primary objectives were:</p> <ul style="list-style-type: none"> - to secure better access to Mexico; - to safeguard and improve the gains made in the FTA; and, - to guarantee and improve Canada’s position as an attractive investment location in North America. <p>It is clear that these objectives have been achieved. The FTA</p>	Links NAFTA objectives to building on and protecting advances made in the FTA; Provides a clear articulation of Canada’s central objectives, as viewed

Speaking Engagement	Quote	Significance
	has been good for Canada and the proposed [NAFTA] will build on that success”	at the highest levels of government.
Notes for an address by Michael Wilson, Third Reading of Bill C-91 December 10, 1992.	“opponents [of Bill C-91] say that drug prices will soar as a result of Bill C-91. They won’t. They haven’t in the past and they won’t in the future. The [Patented Medicines Prices Review] Board has been given new power over both new and existing patented drugs. These powers include the ability to roll back prices, recover excessive revenues, impose fines and imprison offenders. This Bill has teeth – sharp teeth.”	Shows how the record of drug pricing under the FTA-era institution was used to justify further IP protections and a strengthened PMPRB.
Notes for Michael Wilson Speech on Bill C-91 to Senate committee January 21, 1993	“Since 1987, when Bill C-22 was passed, the international community has move significantly in the direction of stronger patent protection. Canada, the only developed nation with compulsory licensing of medicines, was becoming more and more isolated on this issue... Meeting international trade obligations is one important reason for moving forward with this legislation... Bill C-91 moves us closer to the international competition... innovative drug companies have already announce over \$650 million in new investments for Canadian locations...” [the prices of patented medicines] will continue to be under the close control of the [PMPRB].”	Companies continued to increase their investment commitments to help Minister Wilson make his case for the completion of Bill C-91.
Minister’s Orator for University of Toronto Conference “Transcending Boundaries” January 15, 1993	“there is an accession clause providing for other countries or groups of countries to join the NAFTA. In this way, the NAFTA creates an important precedent for trade and economic co-operation between industrialized countries and developing countries.”	Provides a good example of the pump-priming argument and how NAFTA was designed as a “template” agreement.
Speech on Bill C-91 to the Senate [Foreign Relations] Committee, January 21, 1993	“Meeting international trade obligations is one important reason for moving forward with this legislation... Any cost increases that might occur will be a result of the average three-year delay of the entry of lower-priced generic products onto the market. This cost increase has nothing whatsoever to do with the price of individual patented medicines. These will continue to be under the close control of the [PMPRB]”	Draws an important distinction between direct costs associated with drug pricing and indirect costs associated with the length of effective patent life. Canadians would not be paying more for a given drug. They would be paying the same price as before, but for a longer period of time.
Atco Ltd. Strategy Conference, Phoenix AZ April 5, 1993	“Canada was one of the first proponents of a world trade organization, conceived to offer a stronger institutional basis for international trade policies. Canada is still very positively disposed to such an institutional framework... Dispute settlement has also been greatly simplified and improved by the FTA... Canadian industry has had positive results in more than half the completed panels to date.”	Shows Canada’s core interest in rules-based trade. Policy makers were aware of how Canada was benefitting from institutionalized dispute settlement.
Senate Foreign	“[Canada] decided that the best way to ensure a prosperous,	Shows the importance

Speaking Engagement	Quote	Significance
Relations Committee, Ottawa ON, May 26, 1993.	competitive Canadian economy was through...rule-based trading regimes, both at the multilateral and regional levels. The key was to secure our trading relationship with our most important partner, the United States. And the Free trade Agreement has accomplished just that.” “The NAFTA improves upon the FTA through...comprehensive coverage of intellectual property...and a strong, improved dispute settlement mechanism.”	Canada placed on the US trading relationship. Intellectual property and dispute settlement were important elements of NAFTA.
Third Reading Debate on Bill C-115, The NAFTA Implementation Act, Ottawa ON, May 27, 1993	Canadian Businesses gain new intellectual property protection in the NAFTA...As the Canadian Economy moves into higher value-added, knowledge-based growth areas, this protection...will protect our ability to expand into the NAFTA area”	Shows an important link and trade-off on intellectual property. Enhanced IP protection would facilitate Canada’s access and expansion into the NAFTA area market.

ANNEX B.1 to Chapter 3 & 4
Chronology of Statues, Regulations and Trade Agreements Cited in Chapter

Statutes of Canada. 1867. *Constitution Act*, 30 & 31 Victoria, c 3. (U.K.). Accessed February 6, 2016, <http://laws-lois.justice.gc.ca/eng/const/FullText.html>

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North American Free Trade Agreement (NAFTA). 1993. *Results of the North American Free Trade Agreement Negotiations: The Legal Texts*. Ottawa: NAFTA Secretariat,

accessed December 20, 2015, <https://www.nafta-sec-alena.org/Home/Legal-Texts/North-American-Free-Trade-Agreement?mvid=2>.

Final Act Embodying the Results of the *Uruguay Round of Multilateral Trade Negotiations Establishing the World Trade Organization* signed at Marrakesh April 15, 1994, 33 I.L.M. 1143.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C of the *Uruguay Round of Multilateral Trade Negotiations Establishing the World Trade Organization*, signed at Marrakesh April 15, 1994 I.L.M. 1143.

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ANNEX C to Chapter 5
Select Chronology of Pharmaceutical Patent Litigation Post-Wellcome (2002):
Patents Held Invalid on Utility Grounds including PM(NOC) Cases

Extracted from “*Expert Report of Bruce Levin, PH.D, Professor of Biostatistics, Columbia University*”³⁸⁴

With due consideration of critique from “*Second Witness Statement of Marcel Brisebois*”³⁸⁵

Case	Year and Citation	Appeals
Merck & Co. Inc. v. Apotex Inc	2005 FC 755	-
Abbott Laboratories v. Canada (Minister of Health)	2005 FC 1095	-
Aventis Pharma Inc. v. Apotex Inc	2005 FC 1283	Affirmed by 2006 FCA 64 Leave to appeal to SCC refused: Aug. 3, 2006
Abbott Laboratories v. Canada (Minister of Health)	2005 FC 1332	Affirmed by 2007 FCA 153
Pfizer Canada Inc. v. Apotex Inc.	2007 FC 26	Affirmed by 2007 FCA 195 Leave to appeal to SCC refused: Nov. 1, 2007
Eli Lilly Canada Inc. v. Apotex Inc.	2008 FC 142	Affirmed by 2009 FCA 97 Leave to appeal to SCC refused: Oct. 22, 2009
Shire Biochem Inc. v. Canada (Minister of Health)	2008 FC 538	-
GlaxoSmithKline Inc. v. Pharmascience Inc.	2008 FC 593	-
Eli Lilly Canada Inc. v. Novopharm Ltd	2009 FC 235	-
Sanofi-Aventis Canada Inc. v. Apotex Inc.	2009 FC 676	Affirmed 2011 FCA 300 Application for leave to appeal to SCC dismissed (July 12,2012).
Ratiopharm Inc. v. Pfizer Ltd.	2009 FC 711	Affirmed by 2010 FCA 204
Lundbeck Canada Inc. v.	2009 FC 1102	-

³⁸⁴ Bruce Levin, “Expert Report of Bruce Levin, Ph.D; Professor of Biostatistics, Columbia University” September 7, 2015 Case No. UNCT/14/2, accessed August 2, 2016, <http://www.italaw.com/sites/default/files/case-documents/italaw4376.pdf>

³⁸⁵ Marcel Brisebois, “Second Witness Statement of Marcel Brisebois” December 7, 2015, Case No. UNCT/14/2, accessed August 2, 2016, https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC7237_En&caseId=C3544

Case	Year and Citation	Appeals
Ratiopharm Inc		
Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.	2010 FC 230	-
Pfizer Canada Inc. v. Ratiopharm Inc	2010 FC 612	-
AstraZeneca Canada Inc. v. Apotex Inc.	2010 FC 714	-
Novopharm Ltd. v. Eli Lilly and Co.	2010 FC 915	Affirmed 2011 FCA 220 Leave to appeal to SCC refused: Dec 8, 2011
Eli Lilly Canada Inc. v. Novopharm Ltd.	2011 FC 1288	Affirmed 2012 FCA 232 (see also: 2009 FC 1018, reversed and remanded 2010 FCA 197) Leave to appeal to SCC refused (May 16, 2013).
AstraZeneca Canada Inc. v. Phamascience Inc.	2012 FC 1189	FCA reversed trial judge (2014 FCA 133), finding inutility allegation justified
Pfizer Canada Inc. v. Pharmascience Inc	2013 FC 120	-
Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd.	2013 FC 283	Affirmed 2013 FCA 244
Alcon Canada Inc. v. Cobalt Pharmaceuticals Company	2014 FC 149	-
AstraZeneca Canada Inc v Apotex Inc	2014 FC 638	Appeal unsuccessful: 2015 FCA 158
Les Laboratoires Servier v. Apotex Inc.	2015 FC 108	-
Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC	2015 FC 125	Notice of Appeal filed (A-120-15)
Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc., *	2015 FC 1156	-
Eli Lilly Canada Inc. v. Hospira Healthcare Corporation *	2016 FC 47	-
Allergan Inc. v. Apotex Inc.*	2016 FC 344	-
*More recent cases not covered in Bruce Levin report.		

FC – Federal Court; FCA - Federal Court of Appeal; SCC – Supreme Court of Canada

ANNEX C.1 to Chapter 5 Patents Held Invalid on Utility Grounds 1980-2015: Pharmaceutical vs. Non-Pharmaceutical Cases

Extracted from “*Expert Report of Bruce Levin, PH.D, Professor of Biostatistics, Columbia University*” With due consideration of critique from “*Second Witness Statement of Marcel Brisebois*”

	Patent Cases in the Pre-2005 Period Involving a Decided Challenge on Grounds of Utility				Patent Cases in the Post-2005 Period Involving a Decided Challenge on Grounds of Utility			
	Patent found <i>invalid</i> on utility grounds	Patent found <i>valid</i> on utility grounds	Total	% of all <i>invalid</i> on utility grounds ***	Patent found <i>invalid</i> on utility grounds	Patent found <i>valid</i> on utility grounds	Total	% of all <i>invalid</i> on utility grounds ***
Pharmaceutical	0	3	3	0%	24*	39*	63	100%
Non-pharmaceutical	2	22	24	100%	0	6**	6**	0%
Total	2	25	27		24*	45*	69**	

*According to Levin’s chart (above) these figures appear to be misstated and should read 24 pharmaceutical cases invalid and 39 pharmaceutical cases valid in the post-2005 period. Per Brisebois’ identification, one pharmaceutical case from 2014 was missing. However, this was a duplicate PM(NOC) ruling and this matter had already been litigated by another company with the patent upheld and thus was already counted by Levin. As such, the chart has not been amended to reflect Brisebois’ recommendation on this case.

**According to Brisebois one non-pharmaceutical case should also be removed from analysis versus Levin’s original 8. This recommendation is reflected above. Brisebois also argues that there was in fact one invalidation of a non-Pharmaceutical patent post-2015. However, this requires double counting as the case involved many different patent claims some of which were held invalid but others held valid. Given that the result of litigation did provide market exclusivity on those claims upheld, it does not seem appropriate to include it as an invalidated patent. While this likely should be counted as ‘valid’, as a compromise between Brisebois and Levin, rather than double counting, this case has similarly been removed from the analysis yielding 6 total for non-pharmaceutical cases held valid. The case in question is Eurocopter v. Bell Helicopter Textron Canada Ltee, 2013 FCA 219.

***Column added by Author: Not included in Levin’s analysis

Note: Given some controversy about included cases the present analysis does not comment on the question of statistical significance that Levin finds between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents. The chart is primarily provided in annex for illustration rather than statistical purposes and has not been updated to include at least 3 additional 2015-16 pharmaceutical patents held invalid, and 2 pharmaceutical patents held valid since Levin’s analysis. It should be noted that the increase in pharmaceutical utility litigation is itself an important outcome even if those challenges are not always successful. As such, the present analysis gives little weight to the value of the denominator, instead privileging the chronology of actual invalidation rulings. Perhaps a more interesting comparison is the percentage of invalidity rulings between pharmaceutical and non-pharmaceutical patents (highlighted in bold). On balance, there is more than enough evidence to suggest a meaningful constraint on patentable utility in Canada.

ANNEX D to Chapter 6

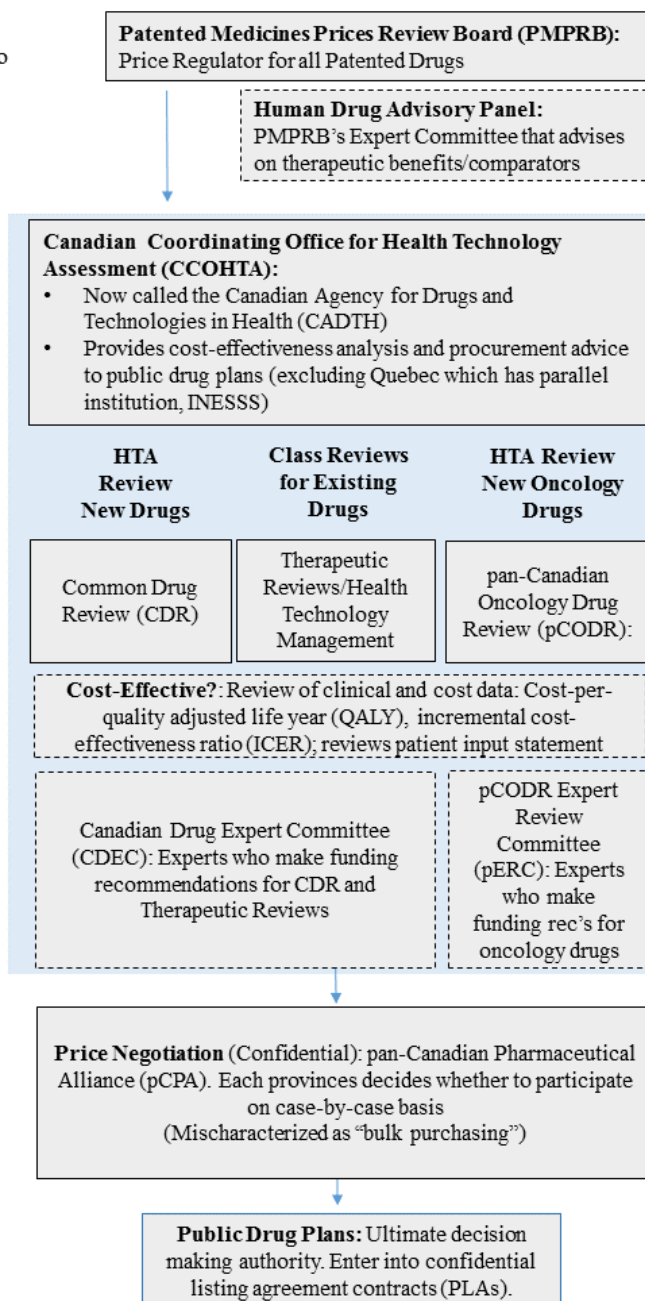
Flow chart of Select Canadian Price Regulation, Health Technology Assessment, and Negotiation Institutions

Price Regulation:
Sets price ceiling to protect consumers from otherwise unrestricted patent protection

HTA:
Helps payers filter what patented technologies should be paid for; at what price; and for whom (under what criteria)

Expert Review:
and application of cost-effectiveness methodology for funding recommendation to gov't

Price Negotiations:
Uses HTA advice and joint "buying power" to further constrain patented drug prices



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